

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO**

D. MARIA SCHMIDT, as Personal
Representative for the Estate of Dakotah
Dedios, Deceased, and RICHALINE DEDIOS,

Plaintiffs,

vs.

No. CIV 19-0933 JB/SCY

INTERNATIONAL PLAYTHINGS LLC;
EPOCH COMPANY, LTD; EPOCH
EVERLASTING PLAY, LLC; WALMART,
INC and MARIE SHORT,

Defendants.

MEMORANDUM OPINION AND ORDER

THIS MATTER comes before the Court on: (i) Defendant Epoch Everlasting Play, LLC's Motion to Strike and Limit Testimony of Plaintiffs' Experts Dennis Brickman, PE and Joseph Mohorovic, CPSM, filed November 19, 2020 (Doc. 100)("Motion to Limit"); and (ii) Defendant Epoch Everlasting Play, LLC's Motion For Partial Summary Judgment on Count III of Plaintiffs' First Amended Complaint -- Negligence Per Se, filed December 1, 2020 (Doc. 105)("MSJ"). The Court held a hearing on April 1, 2021. See Clerk's Minutes at 1, filed April 1, 2021 (Doc. 155). The primary issues are: (i) whether flocked toys are categorically intended for use by children under three years of age under 16 C.F.R. § 1501.2; (ii) whether Defendant Epoch Everlasting Play, LLC ("Epoch Everlasting") is negligent per se, because the Calico Critters Yellow Labrador Twins toy, on which deceased Dakotah Dedios aspirated and choked to death, was a toy with small parts intended for use by children under three years of age in violation of 16 C.F.R. § 1500.18(a)(9); (iii) whether the Court should limit the testimony of the Plaintiffs' experts Dennis Brickman, Professional Engineer ("P.E.") and Joseph Mohorovic, Certified Product Safety Manager ("C.P.S.M."), and Epoch Everlasting's experts Mary Toro and Dr. Carol Pollack-Nelson, who seek

to testify on their interpretations of the federal regulatory scheme banning hazardous toys, because experts may not testify to their interpretations of federal regulations; and (iv) whether the Court should preclude the experts from opining whether the Calico Critters Yellow Labrador Twins toy was intended for use by children younger than three years of age under 16 C.F.R. §§ 1500.18(a)(9) and 1501.2. The Court concludes that: (i) § 1501.2 is ambiguous, because the regulation's plain language can be interpreted reasonably in two ways; the Court considers, therefore, the legislative history, and concludes that flocked toys are categorically intended for use by children under three years of age; (ii) Epoch Everlasting is negligent per se, because it is undisputed that the Calico Critters Yellow Labrador Twins toy has small parts that present a choking hazard and, as a flocked toy, was intended for use by children under three years of age in violation of 16 C.F.R. § 1500.18(a)(9); (iii) the experts may not testify on their interpretations of the federal regulatory scheme banning hazardous toys, because it is for the Court and not for the jury to decide what the law is; (iv) the experts may not opine whether the Calico Critters Yellow Labrador Twins toy was intended for use by children younger than three years of age, because flocked toys are intended definitively for use by children under three years of age under § 1501.2; and (v) the experts may testify about the factual issues related to other counts. Accordingly, the Court: (i) grants in part and denies in part the Motion to Limit; the experts may testify about the factual issues going to other counts, for instance negligence, but not the legal interpretation that go to negligence per se, and (ii) denies the MSJ.

FACTUAL BACKGROUND

The Court sets forth two factual sections to decide the Motion to Limit and the MSJ. The first factual section sets forth the factual background upon which the Court relies for purposes of the Motion to Limit, and the Court takes its facts from the Complaint for Wrongful Death, Loss of

Consortium, Personal Injury, and Punitive Damages, filed October 3, 2019 (Doc. 1-3)(“Complaint”); the Investigative Report, filed January 15, 2021 (Doc. 121-1)(“Mohorovic Report”); the Investigative Report, filed January 15, 2021 (Doc. 121-2)(“Brickman Report”); Report, filed January 15, 2021 (Doc. 121-8)(“Toro Report”); and the Age Determination: Calico Critters -- Yellow Labrador Twins September 25, 2020, at 8, 51, filed January 15, 2021 (Doc. 121-9)(“Pollack-Nelson Report”). The Court makes the best findings of fact it can at this stage of the proceedings for the Motion to Limit, but they are not binding on the Court or the parties or at trial on the merits. The second factual section contains the facts upon which the Court relies for the purposes of the MSJ, which sets forth the undisputed material facts. See Fed. R. Civ. P. 56.

1. Facts for the Motion to Limit.

1. The Defendants, International Playthings LLC; Epoch Co., Epoch Everlasting, Walmart, and Short, “develop, manufacture, market and sell a line of toys under the name” Calico Critters Yellow Labrador Twins. Complaint ¶¶ 13-15, at 5-6.

2. The Calico Critters Yellow Labrador Twins toy consists of two “miniature animal figures,” and two accessories: a miniature bottle and a pacifier. Complaint ¶¶ 13, 15, 5-6.



Figure 1: The Calico Critters Yellow Labrador Twins toy unpackaged.¹

3. “Both the baby bottle and the pacifier are intended to be placed in the mouth of the Critter and both represent play versions of real-life objects that a child would place in their mouth.” Complaint ¶ 17, ay 7.

4. The dimensions of the Calico Critters Yellow Labrador Twins toy are: (i) Labrador Twin Shiloh is one-and-a-half inch tall; (ii) Labrador Twin Marley is one-and-three-quarters inch tall; (iii) the pacifier accessory is thirty-eight-hundredths of an inch tall; and (iv) the bottle accessory is three-quarters of an inch tall. See Complaint ¶ 17, at 6.



Figure 2: The Calico Critters Yellow Labrador Twins toy with rulers.

¹All of the images are taken from the expert reports. The parties do not mention or otherwise respond to the reports’ images; the Court, therefore, deems the images is undisputed. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the Response will be deemed undisputed unless specifically mention or otherwise respond toed.”).



Figure 3: The Calico Critters Yellow Labrador Twins pacifier accessory with rulers.

5. The toy “invites the end used child to put the pacifier into their mouth” and presents a choking hazard. Complaint ¶ 22, at 9.

6. The Calico Critters Yellow Labrador Twins toy are labeled for children three years old and up, “even though their website specifically states that they can be used by children 2 years of age.” Complaint ¶ 18, at 8.



Figure 4: Image of the front of the Calico Critters Yellow Labrador Twins toy packaging.



Figure 5: Close up image of the 3+ label on the Calico Critters Yellow Labrador Twins packaging.



Figure 6: Close up image of the “CHOKING HAZARD” warning label on the Calico Critters Yellow Labrador Twins toy packaging.

7. On the manufacturer’s website,

[u]nder FAQ, they state:

- Q. I want to buy my child Calico Critters. How old should she be to play with them?
- A. Calico Critters have small parts so should only be given to children under 2 with adult supervision. Three year old is

the best age to introduce Calico to your child, but maybe don't buy the sets with very small accessories. The great thing about Calico Critters is that little children from 3 like them! Whether playing with the critters and furniture or collecting, they are sure to be a hit.

Above, the manufacturer identifies the small parts, but states a 2-year-old can play with them. They even acknowledge that 3-year-olds should not play with sets with very small accessories. But the box of Labrador Twins with small, even tiny, accessories is labeled suitable for 3-year olds.

Complaint ¶ 18, at 8.

8. On May 5, 2018, R. Dedios and her daughter, D. Dedios, who was two years and nine months old at the time, were at a Walmart store in Bernalillo, New Mexico. See Complaint ¶ 23, at 10.

9. D. Dedios “was drawn to the ‘Yellow Labrador Twins’ and was able to access and remove the Yellow Labrador Twins from the shelf.” Complaint ¶ 23, at 10.

10. R. Dedios bought the Calico Critters Yellow Labrador Twins toy. See Complaint ¶ 23, at 10.

11. Five days later, on May 10, 2018, D. Dedios “aspirated the loose pacifier toy that came with the Labrador Twins.” Complaint ¶ 24, at 10.

12. D. Dedios “was taken to the hospital and subsequently was pronounced dead.” Complaint ¶ 24, at 10.

13. D. Dedios died “from choking on the loose pacifier toy on May 10, 2018.” Complaint ¶ 24, at 10 (citing an autopsy report).

2. The Undisputed MSJ Facts.

Epoch Everlasting is a subsidiary of Epoch Co., Ltd. (“Epoch Co.”). See Plaintiffs’ Response in Opposition to Defendant Epoch Everlasting Play, LLC’s Partial Motion for Summary

Judgment on Negligence Per Se Claim § II(B) ¶ 1,² at 8, filed January 15, 2021 (Doc. 123)(“MSJ Response”)(asserting this fact); Defendant Epoch Everlasting Play, LLC’s Reply in Support of Motion for Partial Summary Judgment on Count III of Plaintiff’s Complaint -- Negligence Per Se at 2-5, filed February 4, 2021 (Doc. 131)(“MSJ Reply”).³ Epoch Everlasting is the United States of America based distributor of Epoch Co.’s toys, including the Calico Critters line of products and the Yellow Labrador Twins toy. See MSJ Response § II(B) ¶ 1, at 7 (asserting this fact).⁴ Epoch Co. is the original creator of the Calico Critters line of toys. See MSJ Response § II(B) ¶ 19, at 11 (asserting this fact).⁵ Established in 1958, Epoch Co. is the third largest toy manufacturing company in Japan as of 2019. See MSJ Response § II(B) ¶ 19, at 11 (asserting this fact).⁶ Epoch Co. introduced the Calico Critters line of miniature flocked⁷ animal figures in 1985.

²The Plaintiffs provide additional facts in their MSJ Response; however, they number the additional facts as opposed to using letters as D.N.M. LR-Civ 56.1(b) requires. See D.N.M. LR-Civ 56.1(b)(“Each additional fact” in a response “must be lettered . . .”).

³The MSJ Reply does not mention or otherwise respond to this fact; the Court, therefore, deems this fact undisputed. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the Response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

⁴The MSJ Reply does not mention or otherwise respond to this fact; the Court, therefore, deems this fact undisputed. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the Response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

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⁶The MSJ Reply does not mention or otherwise respond to this fact; the Court, therefore, deems this fact undisputed. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the Response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

⁷“Flocking is the process of depositing small fiber particles onto a surface to produce a velvety texture to increase tactile sensation.” MSJ Response Negligence § II(B) ¶¶ 15 n. 1; MSJ Reply Negligence at 1-7 (not mentioning or otherwise responding to this definition); D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the Response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

See MSJ Response § II(B) ¶ 19, at 11 (asserting this fact).⁸ In November, 2008, Defendant International Playthings, Inc. was sold to an affiliate of Epoch Co. See MSJ Response § II(B) ¶ 19, at 11 (asserting this fact).⁹ International Playthings rebranded itself as Epoch Everlasting around February, 2017. See MSJ Response § II(B) ¶ 19, at 11 (asserting this fact).¹⁰ Plaintiff Richaline Dedios is Dakotah Dedios’ mother. See MSJ ¶ 3, at 3; MSJ Response § II(A) ¶ 3, at 4 (admitting this fact).

a. The Calico Critters Yellow Labrador Twins Toy.

A Calico Critters Yellow Labrador Twins toy consists of two miniature animal figurines, along with two loose accessories: a plastic baby bottle and a pacifier. See MSJ Response § II(B) ¶ 2, at 8 (asserting this fact); Deposition of Alyssa Masterson at 45:1-25 (taken July 1, 2020), filed January 15, 2021 (Doc. 119-12)(“Masterson Depo.”).¹¹ The Calico Critters Yellow Labrador Twins’ packaging has a warning label stating “CHOKING HAZARD--Small parts. Not for children under 3 years.” MSJ Response § II(B) ¶ 18, at 4 (providing a picture of the toy’s

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packaging).¹² The Calico Critters Yellow Labrador Twins packaging has a “3+” label. MSJ Response § II(B) ¶ 18, at 4 (providing a picture of the toy’s packaging). See MSJ ¶ 2, at 3 (stating that the “Yellow Labrador Twins were labeled . . . for children ages 3 and up.”).¹³ Calico Critters Yellow Labrador Twins toy is a flocked¹⁴ toy. See MSJ Response § II(B) ¶ 3, at 8 (asserting this fact); Masterson Depo. at 42:6-21.¹⁵



Figure 7



Figure 8

A Calico Critters Yellow Labrador Twins toy and its accessories fit within the small parts

¹²The MSJ Reply does not mention or otherwise respond to this fact or dispute the image; the Court, therefore, deems this fact and the image admitted. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the Response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

¹³The MSJ Reply does not mention or otherwise respond to the image; the Court, therefore, deems this image is admitted. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the Response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

¹⁴“Flocking is the process of depositing small fiber particles onto a surface to produce a velvety texture to increase tactile sensation.” MSJ Response Negligence § II(B) ¶¶ 15 n. 1; MSJ Reply Negligence at 1-7 (not disputing this definition).

¹⁵The MSJ Reply does not mention or otherwise respond to this fact; the Court, therefore, deems this fact undisputed. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the Response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

cylinder.¹⁶ See MSJ Response § II(B) ¶ 4, at 8 (asserting this fact); Masterson Depo. at 45:3-48:15; Deposition of Mary Toro at 37:21-38:4 (taken November 24, 2020), filed January 15, 2021

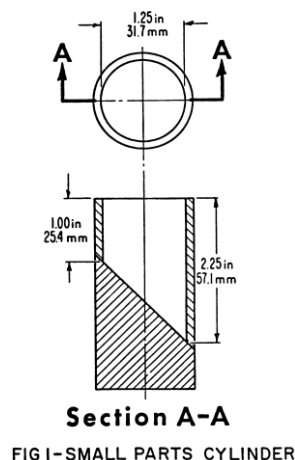
¹⁶A small parts cylinder is a cylindrical measuring device used to test whether a toy or children's article complies with 16 C.F.R. §§ 1501, 1500.18(a)(9). See 16 C.F.R. § 1501.4(a). Section 1501.4(a) provides:

No toy or other children's article subject to § 1500.18(a)(9) and to this part 1501 shall be small enough to fit entirely within a cylinder with the dimensions shown in Figure 1, when tested in accordance with the procedure in paragraph (b) of this section. In testing to ensure compliance with this regulation, the dimensions of the Commission's test cylinder will be no greater than those shown in Figure 1. (In addition, for compliance purposes, the English dimensions shall be used. The metric approximations are included only for convenience.).

16 C.F.R. § 1501.4(a). Section 1501.4(b)(1) explains how a toy is tested: "Place the article, without compressing it, into the cylinder. If the article fits entirely within the cylinder, in any orientation, it fails to comply with the test procedure. (Test any detached components of the article the same way.)." If a toy fails the test -- if it "does not fit entirely within the cylinder" --

[s]ubject it to the appropriate "use and abuse" tests of 16 CFR 1500.51 and 1500.52 (excluding the bite tests of §§ 1500.51(c) and 1500.52(c)). Any components or pieces (excluding paper, fabric, yarn, fuzz, elastic, and string) which have become detached from the article as a result of the use and abuse testing shall be placed into the cylinder, one at a time. If any such components or pieces fit entirely within the cylinder, in any orientation and without being compressed, the article fails to comply with the test procedure.

16 C.F.R. § 1501.4(b)(2). Section 1501.4 provides a figure with dimensions of the cylinder:



16 C.F.R. § 1501.4(b)(2), Fig. 1.

(Doc. 119-13)(“Toro Depo.”); Deposition of Mary Toro at 37:21-38:4 (taken November 24, 2020), filed January 15, 2021 (Doc. 119-13)(“Toro Depo.”); Deposition of Dr. Carol Pollack-Nelson at 47:12-19 (taken December 9, 2020), filed January 15, 2021 (Doc. 119-14)(“Pollack-Nelson Depo.”).¹⁷



Figure 9: Pictures of Calico Critters Yellow Labrador Twins toy and its accessories within the small parts cylinder.¹⁸

The greatest hazard and most dangerous aspect of the Calico Critters Yellow Labrador Twins is the potential that a child can choke on the pacifier and bottle accessory. See MSJ Response § II(B) ¶¶ 11-12, at 9 (asserting this fact); Pollack-Nelson Depo. at 69:1-7; id. at 76:4-7.¹⁹ For children that are still mouthing, which is mostly children younger than three years old, the Calico Critters Yellow Labrador Twins toy is not safe, because it has small parts. See MSJ

¹⁷The MSJ Reply does not mention or otherwise respond to this fact; the Court, therefore, deems this fact undisputed. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the Response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

¹⁸The MSJ Reply does not mention or otherwise respond to the images; the Court, therefore, deems that these images are admitted. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the Response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

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Response § II(B) ¶¶ 11-12, at 9 (asserting this fact); Pollack-Nelson Depo. at 122:3-10.²⁰ Epoch Everlasting has had the Calico Critters Yellow Labrador Twins toy tested to determine whether it adheres to the Consumer Product Safety Act (“CPSA”) regulations. See MSJ ¶ 1, at 3 (asserting this fact); Masterson Depo. at 40:4-42:5 (Masterson, Epoch Everlasting’s Director of Marketing and Strategic Product Development, testifying that “I know that our products are tested to meet the CPSC requirements.”).²¹ Epoch Everlasting has never age graded the Calico Critters Yellow Labrador Twins toy. See MSJ Response § II(B) ¶ 14, at 10 (asserting this fact); Masterson Depo. at 54:9-13.²² Epoch Everlasting has no knowledge whether a third-party testing company has ever

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²¹Epoch Everlasting contends that it is undisputed that the “Yellow Labrador Twins were tested to CPSC regulations and certified as being appropriate for children ages 3 and up.” MSJ ¶ 1, at 3 (citing Masterson Depo. at 40:4-15; id. at 43:1-2 id. at 44:2-4; id. at 51:1-8; id. at 54:11-25; id. at 55:1-19 id. at 62:6-7). The Plaintiffs dispute this factual assertion, arguing:

Although [Masterson] testified that its products “comply to CPSC regulations” and “are tested to the CPSC regulations,” [Masterson] also admitted that [she] did not know whether its Calico Critters products, including the Yellow Labrador Twins, fit inside the small parts cylinder. [Masterson Depo.] at 44:5-44:22. Ms. Masterson further testified, on behalf of Defendant EEP, that the toy had never been age-graded by EEP and she had no knowledge about whether a third party testing company had ever performed age grading. SGS, EEP’s third party testing company, did not perform age grading on the Yellow Labrador Twins. [Masterson Depo.] at 54:9-13; 61:20-23; 63:1-20 . And [Masterson] further testified that no one at the company performed age grading on any of the Calico Critters line of products. Id. at 55:20-23.

MSJ Response at ¶ 1 at 2-3. The Court concludes that Masterson’s deposition testimony only supports that “Epoch Everlasting has had the Calico Critters Yellow Labrador Twins toy tested to CPSC regulations,” and the conclusion that the Calico Critters Yellow Labrador Twins comply with regulations is a legal conclusion that the Court will address in its Analysis.

²²The MSJ Reply does not mention or otherwise respond to this fact; the Court, therefore, deems this fact undisputed. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the Response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

age graded the Calico Critters Yellow Labrador Twins toy. See MSJ Response § II(B) ¶ 14, at 10 (asserting this fact); Masterson Depo. at 54:14-55:23.²³ Epoch Everlasting’s third-party testing company has not performed an age grading test on the Calico Critters Yellow Labrador Twins toy. See MSJ Response § II(B) ¶ 14, at 10 (asserting this fact); Masterson Depo. at 54:20-55:23; id. at 61:20-23; id. at 63:1-20.²⁴

b. R. Dedios Buys the Calico Critters Yellow Labrador Twins Toy for D. Dedios, and D. Dedios Chokes to Death on the Toy.

R. Dedios bought a Calico Critters Yellow Labrador Twins toy for D. Dedios. See MSJ ¶ 3, at 4 (asserting this fact); MSJ Response § II(B) ¶¶ 3-4, at 4-5 (admitting this fact). D. Dedios was about two-and-a-half years old when R. Dedios purchased the Calico Critter Yellow Labrador Twins toy. See MSJ ¶ 3, at 3 (asserting this fact).²⁵ R. Dedios saw that the packaging on the

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In the Response, the Plaintiffs assert that the parties’ experts made various conclusions. See MSJ Response § II(B) ¶¶ 16-17, at 10 (citing Pollack-Nelson Depo. at 26:9-20; Declaration of Dennis B. Brickman at 101, dated January 12, 2021, filed January 15, 2021 (Doc. 119-15)(“Brickman Decl.”); Declaration of Joe Mohorovic at 25, dated January 12, 2021, filed January 15, 2021 (Doc. 119-11)(“Mohorovic Decl.”)). Although Epoch Everlasting does mention or otherwise respond to what these experts testified to, the fact that an expert testified to a conclusion does not amount to fact for rule 56 purposes. Furthermore, these experts testified to legal conclusions, which are the Court’s domain. See Pollack-Nelson Depo. at 26:9-20 (concluding that the Calico Critters Yellow Labrador Twins toy is properly age graded for children three years and up); Brickman Decl. at 101 (“The age grading by the manufacturer of 3+ on the subject product package is not reasonable; Mohorovic Decl. at 25 (“The subject products were labelled ‘3+’ and ‘Not for children under 3 years.’ This is the manufacturer’s stated intent, but it is not reasonable.”).

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Calico Critter Yellow Labrador Twins toy included a warning that it was for ages three and up. See MSJ ¶ 5, at 5-6 (asserting fact); MSJ Response § II(A) ¶¶ 4-5, at 5-6 (admitting this fact); Deposition of Richaline Dedios at 61:14-18 (taken May 4, 2020), filed November 25, 2020 (Doc 102-1)(“R. Dedios Depo.”).²⁶ On May 10, 2018, D. Dedios aspirated on the Calico Critter Yellow

²⁶The parties purport to dispute whether R. Dedios “knew the product was meant for children ages 3 and up.” MSJ Negligence ¶ 6, a 2 (citing R. Dedios Depo. 65:14-22). See MSJ Response Negligence § II(A) ¶ 4, at 5 (“Denied that Ms. Dedios ‘knew the product was meant for children ages 3 and up.’”). The Plaintiffs “[a]dmit[] that Ms. Dedios bought the toy and saw the ‘three and up’ label,” but “[d]en[y] that Ms. Dedios ‘knew the product was meant for children ages 3 and up.’” MSJ Response Negligence § II(A) ¶ 4, at 5. The deposition testimony that Epoch Everlasting cites reflects that R. Dedios saw the packaging included a “choking hazard . . . warning,” and reflects that R. Dedios admits that she “s[aw] that it was for age three and up”:

Q. Did you see anything on the packaging of the Calico toy that told you it was for a certain age?

A. Yes.

Q. And what did you see?

A. I believe the choking hazard, the warning.

Q. Did you see that it was for age three and up?

A. Yes.

Q. And at that time, was D. Dedios three yet?

A. No.

R. Dedios Depo. 65:14-22. The Plaintiffs dispute R. Dedios “knew” the toy was “meant” for a certain age demographic, because they argue that Epoch Everlasting’s intent was to market toys to children younger than three despite the age label. See MSJ Response Negligence § II(A) ¶ 4, at 5. The Court concludes that the deposition testimony shows that R. Dedios saw the warning and age labels on the packaging and was aware of the significance of these labels; however, even if R. Dedios was aware that the product was labeled for children three years and older and had a choking warning, that does not imply that the Calico Critters Yellow Labrador Twins toy was intended for children three years older and up, as the Court will discuss in the Analysis. See R. Dedios Depo. 65:14-22.

Labrador Twins toy's pacifier accessory, and she choked to death. See MSJ at 2.²⁷

Other children have choked on the Calico Critter Yellow Labrador Twins toy's pacifier accessory. See MSJ Response § II(B) ¶ 24, at 12 (asserting this fact).²⁸ In 2013, a twenty-two-month-old child swallowed and choked on the same toy pacifier that caused Dakota's death. See MSJ Response § II(B) ¶ 24, at 12 (asserting this fact); Mark Saal, Farmington Mom, 911 Dispatcher Hailed for Saving Choking Toddler, Standard-Examiner (July 4, 2013), https://www.standard.net/police-fire/farmington-mom-911-dispatcher-hailed-for-saving-choking-toddler/article_fd79a84e-8d84-5767-992e-98e9f8df3337.html.²⁹ The U.S. Public Interest Research Group, a non-profit safety watchdog group, has identified the Calico Critters toys and its accessories as dangerous choking hazards and seeks to have these toys recalled. See MSJ Response § II(B) ¶ 24, at 12 (asserting this fact)(citing Grace Bromback, Trouble in Toyland 2020, United States Public Interest Research Group Educ. Fund, https://www.dropbox.com/sh/5q7qdkq9dnttqdy/AADJCNiXaBVCERvk0WTdFNla?dl=0&preview=USP_Toyland-Report_Nov20_web.pdf; Phaedra Haywood, Toy Linked to New Mexico Child's Death Tops Watchlist, Santa Fe New Mexican (Nov. 27, 2020), http://www.santafenewmexican.com/news/local_news/toy-linked-to-new-mexico-child-s-death-

²⁷The MSJ Response does not mention or otherwise respond to this fact; the Court, therefore, deems this fact undisputed. See D.N.M. LR-Civ 56.1(b) ("All material facts set forth in the [MSJ] will be deemed undisputed unless specifically mention or otherwise respond toed.").

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tops-watchlist/article_6cb49678-2e96-11eb-8fe3-6ffdaf34150d.html).³⁰ World Against Toys Causing Harm, Inc. (“W.A.T.C.H.”) recently identified Calico Critters toys as one of the “Ten Worst Toys.” MSJ Response § II(B) ¶ 24, at 12 (asserting this fact); W.A.T.C.H. Reveals Its 2020 Nominees for the “10 Worst Toys” This Holiday Season, W.A.T.C.H., filed January 15, 2021 (Doc. 123-1)(“W.A.T.C.H. Press Release”).³¹

PROCEDURAL HISTORY

On August 16, 2019, the Plaintiffs filed the Complaint in state court. See Complaint ¶¶ 59-63, at 18-19. The Plaintiffs also filed a demand for jury trial. See Jury Demand at 20, filed October 3, 2020 (Doc. 1-3). In the Complaint, the Plaintiffs assert four counts against the Defendants: (i) strict products liability; (ii) negligence; (iii) negligence per se; and (iv) breach of implied warranty of merchantability. See Complaint ¶¶ 27-58, at 11-18. The Plaintiffs seek damages for wrongful death and loss of consortium damages, as well as punitive damages. See Complaint ¶¶ 58-63, at 17-18.

1. The Notice of Removal, the Motion to Remand, and the MOO Concluding that The Plaintiffs Fraudulently Joined Defendant Marie Short, a Non-Diverse Party and the Store Manager at Defendant Walmart, Inc., to Defeat Federal Diversity Jurisdiction.

On October 3, 2019, Epoch Everlasting filed a Notice of Removal in federal court based on diversity jurisdiction. See Notice of Removal ¶¶ 3-10, at 1-4. Epoch Everlasting filed the Amended Notice of Removal, alleging that: (i) the Plaintiffs seek more than \$75,000; (ii) complete

³⁰The MSJ Reply does not mention or otherwise respond to this fact; the Court, therefore, deems this fact undisputed. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

³¹The MSJ Reply does not mention or otherwise respond to this fact; the Court, therefore, deems this fact undisputed. See D.N.M. LR-Civ 56.1(b) (“All material facts set forth in the response will be deemed undisputed unless specifically mention or otherwise respond toed.”).

diversity exists because: (a) the Plaintiffs are both citizens of New Mexico; (b) “[n]o Defendant is a citizen or has its principal place of business in New Mexico. No member of an any LLC defendant is a citizen of New Mexico;” and (c) the Plaintiffs “fraudulently joined Marie Short to defeat diversity jurisdiction,” so her citizenship should be ignored for the purposes of determining diversity. Amended Notice of Removal ¶¶ 5-14, at 2-4, filed November 6, 2019 (Doc 22).

On November 4, 2020, the Plaintiffs moved to remand the case to state court. See Plaintiffs’ Motion to Remand at 1, filed November 4, 2020 (Doc. 18). The Plaintiffs argue that: (i) the Court lacks subject-matter jurisdiction because complete diversity does not exist; and (ii) that the Notice of Removal is procedurally defective, because not all the Defendants have joined or consented to the Notice of Removal under 28 U.S.C. § 1446(b)(2)(A). See Motion to Remand at 1; Motion to Remand Memo at 2-15.

The Court issued its Memorandum Opinion and Order. See Schmidt v. Int’l Playthings LLC, No. CIV 19-0933 JB/SCY, 2020 WL 7024252, at *1 (D.N.M. Nov. 30, 2020), filed November 30, 2020 (Doc. 103)(“MOO”). In the MOO, the Court concludes:

(i) that Epoch Everlasting has shown that there is “no possibility” that Schmidt and Dedios can establish a cause of action against Short under a theory of strict products liability, because Short is not a seller or supplier, and there is “no possibility” that Schmidt and Dedios can establish a cause of action against Short under a theory of negligence, because there is no applicable duty under New Mexico law; and (ii) that the Notice of Removal is not procedurally defective, because the Notice of Removal satisfies the unanimity rule. Accordingly, because the Court has diversity jurisdiction under 28 U.S.C. § 1332(a)(1), the Court will deny the Motion to Remand.

MOO, 2020 WL 7024252, at *1.

After the Court issued its MOO, the Plaintiffs moved to “dismiss with prejudice all claims that were or could have been asserted against Defendants Walmart, Inc. and Marie Short. All Defendants consent to this stipulated dismissal.” Stipulation of Dismissal with Prejudice of Defendants Walmart, Inc. and Marie Short at 1, filed December 7, 2020 (Doc. 108).

2. Epoch Everlasting's MSJ.

Epoch Everlasting requests that the Court grant summary judgment on the Plaintiffs' claim of negligence per se. See MSJ at 1. Epoch Everlasting argues that the Plaintiffs "are not entitled to a presumption of negligence per se against" Epoch Everlasting, "because the company did not violate any statutes or regulations in its distribution of the Yellow Labrador Twins. The regulations at issue are self-explanatory and do not automatically ban flocked toys like the Yellow Labrador Twins." MSJ at 4-5. Epoch Everlasting contends that, under New Mexico law, to establish a claim of negligence per se, a plaintiff must meet four elements:

"(1) there must be a statute which prescribes certain actions or defines a standard of conduct, either explicitly or implicitly, (2) the defendant must violate the statute, (3) the plaintiff must be in the class of persons sought to be protected by the statute, and (4) the harm or injury to the plaintiff must generally be of the type the legislature through the statute sought to prevent."

MSJ at 5 (quoting Archibeque v. Homrich, 1975-NMSC-066, ¶ 15, 543 P.2d 820).

First, Epoch Everlasting argues that 16 C.F.R. § 1501.1, which Epoch Everlasting calls the "Small Parts Regulation," does not apply to the Yellow Labrador Twins toy, because the toy is intended for children ages three and above. MSJ at 5. Here, Epoch Everlasting argues that § 1501 "does not apply to the Yellow Labrador Twins because the toy was intended for use by children over 3 years of age," meaning that the toy is "permitted to have small parts." MSJ at 7 (citing 16 C.F.R. § 1501.2(c), which states that the regulation "does not apply to toys or articles which are intended solely for use by children 3 years of age or older"). Epoch Everlasting contends that, before it distributed the Yellow Labrador Twins toy, it had the toy tested and certified as appropriate for children ages three and up, and that the toy is intended for children ages three and up. See MSJ at 7. Epoch Everlasting contends that R. Dedios did not use the toy as intended, because R. Dedios bought the toy for D. Dedios, even though the toy's packaging identifies as intended for children ages three and up and D. Dedios was not three years old. See MSJ at 7.

Next, Epoch Everlasting contends that, because Epoch Co. “designed the product, its packaging and had it tested for safety by an independent company,” it does not violate 16 C.F.R. § 1500.18. MSJ at 8. Epoch Everlasting argues that its “expert Dr. Carrol Pollack-Nelson age graded the Yellow Labrador Twins and again found the product to be for children ages 3 and up.” MSJ at 8. Epoch Everlasting contends that Dr. Pollack-Nelson examined all four factors, and determined that the Yellow Labrador Twins toy is intended for ages three and up. See MSJ at 8-9.

3. The MSJ Response.

The Plaintiffs respond and argue that Epoch Everlasting is negligent per se, because the Yellow Labrador Twins toy and its accessories, “violates the regulations issued by the Consumer Product Safety Commission (‘CPSC’), in particular the ‘small parts regulations’ pertaining to children’s toys.” MSJ Response at 1-2. The Plaintiffs argue that the “small parts regulations apply as a matter of law to a long list of toys and other articles that are clearly intended for use by children under 3 years of age, including ‘stuffed, plush, and flocked animals and other figures,’ like the flocked Yellow Labrador Twins” toy. MSJ Response at 14 (quoting 16 C.F.R. § 1501.2(a), and citing 16 C.F.R. § 1501.1). The Plaintiffs contend that the CPSC “intended to limit the toys subject to the small parts regulations only to those toys that were intended for use by children under three years of age,” and if the CPSC “had not intended to include any toys on the list that were intended for use by children over three years of age, as” Epoch Everlasting “contends, the CPSC would not have needed to use such language.” MSJ Response at 15.

The Plaintiffs explain that a “toy subject to Section 1500.18(a)(9) is deemed hazardous if it fits, without compression, entirely into a ‘small toy cylinder’ -- i.e., a cylinder with a diameter of one and one-quarter inches and a depth which slopes at a 45° angle from one inch to two-and-one-quarter inches.” MSJ Response at 15 (quoting 16 C.F.R. § 1501.4(a), (b)(1)). The Plaintiffs

argue that the small parts regulations still apply even where a toy is labeled as suitable for children ages three and up, “if the toy is really intended for use by children under 3 years of age.” MSJ Response at 16.

In determining which toys and other articles are intended for use by children under three years of age, federal regulations require one to consider: “the manufacturer’s stated intent (such as on a label) if it is a reasonable one; the advertising, promotion, and marketing of the article; and whether the article is commonly recognized as being intended for children under 3.” 16 C.F.R. § 1501.2(b).

MSJ Response at 16. The Plaintiffs contend that not a single factor is dispositive and expert testimony is useful to a jury. See MSJ Response at 16 (citing United States v. Toys “R” Us, Inc., 754 F. Supp. 1050, 1054 (D.N.J. 1991)(Barry, J.)).

The Plaintiffs argue that there are questions of material fact that preclude summary judgment. See MSJ Response at 19. The Plaintiffs contend that “certain types of toys, including ‘stuffed, plush, and flocked animals and other figures,’ like the flocked Yellow Labrador Twins at issue here, are automatically subject to the small parts regulations as a matter of law.” MSJ Response at 19. The Plaintiffs argue that there is a factual question whether the Yellow Labrador twins comply with the small parts regulations. See MSJ Response at 19-20. The Plaintiffs argue that the small parts regulations applies if the toy is intended for use by children under three years of age and notes that their expert disagrees with Epoch Everlasting’s human factors expert that the Yellow Labrador Twins toy “is properly age graded as intended solely for use by children ages three and up.” MSJ Response at 20.

4. The MSJ Reply.

Epoch Everlasting replies, and argues that the Yellow Labrador Twins toy “is not subject to the Small Parts Regulation, 16 C.F.R. § 1501.1 et seq. because the toy was not intended for children below the age of three.” Defendant Epoch Everlasting Play, LLC’s Reply in Support of Motion for Partial Summary Judgment on Count III of Plaintiffs’ Complaint -- Negligence Per Se

at 1-2, filed February 4, 2021 (Doc. 131)(“MSJ Reply”). Epoch Everlasting argues that “[t]oys that are age-graded as appropriate for children ages 3 and up are permitted to have small parts. Since the Yellow Labrador Twins was age-graded as appropriate for children ages 3 and up, there was no violation 16 C.F.R. § 1500.18.” MSJ Reply at 2. Epoch Everlasting contends that if a toy is flocked, it is automatically banned as hazardous under 16 C.F.R. § 1501.2. See MSJ Reply at 5. Epoch Everlasting contends:

To determine whether the Small Parts Regulation applies to a specific toy, Consumer Product Safety Commission (“CPSC”) staff perform an age determination. Depending upon the age for which a specific toy is intended, it may or may not be permitted to have “small parts.” Although the product at issue in this litigation is flocked, one must still perform the Section 1501.2(b) analysis to determine whether the toy is intended for children under three years of age.

MSJ Reply at 6.

Epoch Everlasting contends that an independent company tested, age graded, and certified the Yellow Labrador Twins toys as appropriate for children ages three and up. See MSJ Reply at 6 (citing Test Report, filed December 21, 2020 (Doc. 113-4)(“SGS Certification”).³² Epoch Everlasting contends that it

also retained Dr. Carrol Pollack-Nelson, who age-graded the product and determined again that the toy was intended for age 3 and up. Plaintiffs have not attempted to age grade the Yellow Labrador Twins. . . . The Court, not Plaintiffs nor their experts, determines what the law is and interprets the applicable federal regulations.

MSJ Reply at 6 (no citations to the record).

5. The Motion to Limit.

In the Motion to Limit, Epoch Everlasting requests that the Court strike and limit the

³²Epoch Everlasting does not cite the SGS Certification in the factual sections of the MSJ. See MSJ at 3-4. Epoch Everlasting cites the SGS Certification for the first time in support of its contention that the toys are appropriate for children ages three and up in its reply, which is not the appropriate motion to assert undisputed facts. See D.N.M. LR-Civ 56.1(b). Accordingly, the Court will not consider the SGS Certification.

testimony of the Plaintiffs’ experts Brickman and Mohorovic under rule 702 of the Federal Rules of Evidence. See Motion to Limit at 1, 3. Epoch Everlasting contends that under rule 702, “the Court must ‘determine whether the expert is proposing to testify to (1) scientific, technical or other specialized knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.’” Motion to Limit at 3 (quoting United States v. Muldrow, 19 F.3d 1332, 1337 (10th Cir. 1994)). Epoch Everlasting argues that an expert’s opinion must be reliable and may not state legal conclusions, or testify as to issues of law governing the jury’s deliberations. See Motion to Limit at 3 (citing Dodge v. Cotter Corp., 328 F.3d 1212, 1221 (10th Cir. 2003), A.E. By and Through Evans v. InDepo. Sch. Dist. No. 25 of Adair Cnty. Okl., 36 F.2d 472, 476 (10th Cir. 1991), and United States Aviation Underwriters, Inc. v. Pilatus Bus. Aircraft, LTD, 582 F.3d 1131, 1130 (10th Cir. 2009)).

Epoch Everlasting asks the Court to limit and exclude “any testimony by Mohorovic or Brickman purporting to interpret federal regulations.” Motion to Limit at 4. Epoch Everlasting argues that

Mohorovic and Brickman are not testifying how the Consumer Product Safety Commission interprets the federal regulations. Plaintiffs’ experts are testifying as to their interpretation of the federal regulations. This subverts the purpose of the Court, who instructs the jury on the law. Plaintiffs’ experts both testify that the product at issue - the Yellow Labrador Twins -- is banned by the federal regulations because the miniature figurines are flocked toy animals. Whether the Yellow Labrador Twins is banned by federal regulation would be a judicial determination, not the subject of expert testimony.

Motion to Limit at 5.

6. The Response to the Motion to Limit.

In response, the Plaintiffs argue that Mohorovic and Brickman’s testimony is proper. See Plaintiffs’ Response in Opposition to Defendant Epoch Everlasting Play, LLC’s Motion to Limit and Limit the Testimony of Plaintiffs’ Experts Dennis Brickman, PE, and Joseph Mohorovic,

CPSM at 1, filed January 15, 2021 (Doc. 121)(“Response Motion to Limit”). The Plaintiffs argue that, “[a]lthough Epoch [Everlasting] relies on Rule 702 as the basis for its Motion to Limit the experts’ testimony, Epoch [Everlasting] actually does not challenge the qualifications of the experts or the reliability or the relevancy of their testimony or conclusions.” Response Motion to Limit at 1. The Plaintiffs contend that the rule prohibiting experts from testifying on their interpretations of law has exceptions:

It is a well-settled exception to this general rule that the Court has broad discretion to permit a qualified expert to testify regarding the meaning and application of federal regulations if the applicable regulatory scheme is complex and beyond the common understanding of a typical juror, and the expert’s testimony will assist the jury in understanding the regulatory process and the parties’ compliance with those regulations. See Antrim Pharmaceuticals LLC v. Bio-Pharm, Inc., 950 F.2d 423, 430-31 (7th Cir. 2020); United States v. Offill, 666 F.3d 168, 175 (4th Cir. 2011); United States v. Buchanan, 787 F.2d 477, 483-84 (10th Cir. 1986); United States v. Gold, 743 F.2d 800, 817 (11th Cir. 1984); Env’t Defense Fund, Inc. v. Lamphier, 714 F.2d 331, 340 (4th Cir. 1983); In re Bard IVC Filter Prods. Liab. Litig., 2017 WL 6523833, at *4 (D. Ariz. Dec. 21, 2017); U.S. ex rel. Ruscher v. Omnicare, Inc., No. 4:08-cv-3396, 2105 WL 5178074, at *9 (S.D. Tex. Sept. 3, 2015); United States v. Executive Recycling, Inc., Crim. No. 11-cr-00376-WJM, 2012 WL 5989447, at *2 n.3 (D. Colo. Nov. 30, 2012)(distinguishing U.S. Aviation Underwriters, 582 F.3d at 1150-51); Securities and Exchange Comm’n v. Big Apple Consulting U.S., Inc., No. 6:09-cv-1963-Orl-28GJK, 2011 WL 3753581, at *4 (M.D. Fla. Aug. 25, 2011); In re Wellbutrin SR Antitrust Litig., Nos. 04-5525, 04-5898, 2010 WL 8425189, at *3 (E.D. Pa. Mar. 31, 2010). Similarly, “an expert is not prohibited from testifying about the standard of care in his industry merely because federal regulations form part of those standards.” Martinez v. Continental Tire the Americas, LLC, No. 1:17-cv-00922-KWR-JFR, 2020 WL 5943691, at *5 (D.N.M. Oct. 7, 2020); see In re Suboxone (Buprenorphine Hydrochloride Naloxone) Antitrust Litig., MDL No. 2445, 2020 WL 6887885, at *45 (E.D. Pa., Nov. 24, 2020); Mirena IUD Prods. Litig., 169 F. Supp. 3d 396, 467-68 (S.D.N.Y. 2016); In re Yasmin & YAZ (Drospirenone) Marketing, Sales Practices and Products Liability Litigation, MDL No. 2100, 2011 WL 6302287, at *12 (S.D. Ill. Dec. 16, 2011).

Response Motion to Limit at 2.

The Plaintiffs argue that a person “cannot usually eyeball a toy to determine whether it is a banned, hazardous substance; it is therefore unsurprising that Plaintiffs’ and Defendant’s experts address this issue and differ in their opinions.” Response Motion to Limit at 7. The Plaintiffs

contend that an expert must test whether a toy complies with the regulations under §§ 1500.18(a)(9); 1501.4(a), (b)(1). See Response Motion to Limit at 7. Turning to the experts' testimony, the Plaintiff contends that both Mohorovic and Brickman examined, and tested, the Yellow Labrador Twins toy, and concluded that the toy and its accessories are intended for use by children under three years old. See Response Motion to Limit at 8-10 (citing Investigative Report, filed January 15, 2021 (Doc. 121-1)("Mohorovic Report"), and Investigative Report, filed January 15, 2021 (Doc. 121-2)("Brickman Report")). The Plaintiffs explain that the experts will offer testimony about their tests and conclusions, and that "Mohorovic also intends to offer testimony regarding whether Defendant Epoch exercised due care under the applicable regulations and acted within consumer product safety management best practices." Response Motion to Limit at 8-10.

The Plaintiffs argue that

Mr. Brickman's and Mr. Mohorovic's testimony are intended to assist the jury to understand the evidence presented against the backdrop of the federal regulations governing Defendant Epoch's toys. Given the complex nature of the federal regulations governing children's toys and the testing required under the regulations, the experts' testimony regarding the meaning and application of those regulations will "assist the trier of fact to understand the evidence [and] to determine [] fact[s] in issue" -- not to simply tell the jury what the law is or what conclusion it should reach in the case.

Response Motion to Limit at 13 (quoting United States v. Buchanan, 787 F.2d 477 (10th Cir. 1986)). The Plaintiffs also contend that Epoch Everlasting's expert, Mary Toro, should also be precluded from testifying to her interpretation of the federal regulations:

Not surprisingly, although contrary to Defendant Epoch's argument here, Epoch's expert regarding the age grading of the Yellow Labrador Twins, Ms. Mary Toro, includes opinions regarding the federal regulations governing children's toys throughout her expert report -- just like Mr. Brickman. Plaintiffs do not object to Ms. Toro's testimony under Rule 702.

Response Motion to Limit at 9 n.6 (citing Report, filed January 15, 2021 (Doc. 121-8)("Toro Report")).

7. The Reply to the Motion to Limit.

Epoch Everlasting replies and argues that experts cannot testify “as to *their* interpretation of the federal regulations.” Defendant Epoch Everlasting Play, LLC’s Reply in Support of Motion to Limit and Limit Testimony of Plaintiffs’ Experts Dennis Brickman, PE and Joseph Mohorovic, at 2, CPSM, filed February 5, 2021 (Doc. 134)(“Reply Motion to Limit”)(emphasis in the original).

Epoch Everlasting argues that its expert, Mary Toro, can testify, because:

Toro’s expert testimony assists the trier of fact to understand the evidence in this matter because she is testifying how the CPSC interprets federal regulations, including the Small Parts Regulation, based on her extensive experience employed by the CPSC. Ms. Toro’s testimony outlines the chronology of the Federal Hazardous Substances Act, 15 U.S.C. § 1261(2)(f) and other federal regulations. She is not testifying to her interpretation of the federal regulations, unlike Mr. Brickman and Mr. Mohorovic. It is not the job of an expert to instruct the jury on the applicable law. That is the job of the Court. Whether the product at issue in this litigation is banned by federal regulation is a judicial determination, not the subject of expert testimony. Therefore, any testimony by Mr. Brickman or Mr. Mohorovic interpreting the federal regulations should be limited and excluded.

Reply Motion to Limit at 3.

8. The Hearing.

The Court held a hearing on the MSJ and the Motion to Limit. See Draft Transcript of Hearing (taken April 1, 2021)(“Tr.”).³³ Epoch Everlasting first took up the Motion to Limit and contended that

the plaintiffs’ experts, both of them, contend that under the terms of the regulation at issue here, which is § 1501, that they have in their opinions that this product should never have been marketed, that toys that are flocked in nature are per se banned, that there is no exception, and if they are a flocked animal and they have small parts they’re banned. The [toy] should never been introduced into the market.

Tr. at 8:21-94 (Biehler). Epoch Everlasting argued that 16 C.F.R. § 1501.2 does not ban flocked

³³The Court’s citations to the transcript of the hearing refer to the court reporter’s original, unedited version. Any final transcript may contain slightly different page and/or line numbers.

animals and that expert opinion on what a statute says “invades the province of the Court by telling the jury what the law is,” and is not based on science. Tr. at 9:5-8 (Biehler). Turning to the regulation, Epoch Everlasting contended that § 1501.2 applies to toys that are intended for use by children under three years of age, which “includes among the toys that come within the scope of the statute, flocked animals,” but the small parts regulation does not apply to toys intended solely for use by children older than three years of age. Tr. at 9:13-10:5 (Biehler). Epoch Everlasting argues that “under the very plain terms of the statute it just it does not say that these toys are banned as a matter of law.” Tr. at 10:5-7 (Biehler)(citing Toy Mfrs. of Am., Inc. v. Blumenthal, 806 F. Supp. 336, 347 (D. Conn. 1992)(Burns, J.), aff’d, 986 F.2d 615 (2d Cir. 1992)).

The Court explains what it often does when experts want to testify about the law:

Here’s what I’ve done in similar situations. I’m not saying this is appropriate here, but a lot of times I have law professors or something like that file an affidavit and they draw a motion to strike saying that’s a legal issue. It seems to me that this problem is a legal issue in that I will at some point have to turn to the jury and either say yes, this count of negligence per se is available and then tell them why it’s a violation per se. And generally, in trucking cases . . . where I’ve had these circumstances, I tell them that this is what they need to determine if it violates [the statute or regulation]. But it seems to me in drafting those jury instructions and giving that instruction . . . I make the determination as to whether there is a law that has violated [and] that there is evidence that they have violated [the standard.] And a lot of times with these professors -- I get these affidavits in class actions -- . . . I just turn them into sort of like extra attorneys. . . . [So I will] fully consider[] everything that the experts are saying, just as an additional brief or amicus or something like that, but in the end I have to make the determination as to whether it goes to the jury or not. If you’re right that it doesn’t violate [the regulation, then] . . . maybe that count doesn’t go to the jury, but if it does, it goes to the jury that I’ve made a determination that there is a law . . . that can be used for negligence per se. . . . Generally, I’m the one that tells the jury here’s the law, here’s the per se violation the plaintiff is alleging. And we don’t have experts come in and talk to the jury about whether there is a law or not a law. That’s something that I determine by looking at the New Mexico law, and make the best call I can

Tr. at 11:20-15:16 (Court).

The Plaintiffs explained why they do “not agree with that approach,” because the federal regulatory scheme is complex and expert testimony is helpful to the jury. Tr. at 16:4-25

(Kaufman). The Plaintiffs argued that if the Court disagrees that a flocked toy with small parts is not under § 1501.2(a)'s scope, then the jury would have to hear competing facts whether the Calico Critters Yellow Labrador Twins toy is intended for use by children under three years of age,

but in our view under Daubert [v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993)] (“Daubert”) where the challenge here is whether or not an expert like Mr. Brickman or Mr. Mohorovic can even refer to the federal regulations at all, we believe there is sufficient authority in the case law and under the facts of this case to allow them to testify to those regulations and allow the jury to determine whether or not those regulations were violated.

Tr. at 17:10-18:24 (Kaufman). The Court clarified that the rule here not a Daubert issue, because the Motion to Limit does not implicate the expert's knowledge. See Tr. at 18:25-19:6 (Court). The Plaintiffs contended that it is question of fact whether the Calico Critters Yellow Labrador Twins toy was intended for use by children under three years of age and that experts can testify to the intent. See Tr. at 20:1-24 (Kaufman). The Plaintiffs also argued that, if the Court looks to Federal Register, the CPSC specifically lists flocked toys as categorically within the small parts regulation's scope. See Tr. at 21:1-22:24 (Kaufman).

The Court asked Epoch Everlasting if it concludes that the experts cannot testify whether the small parts regulation applies, whether the experts can then testify to the “factual issue” of intent, so that the jury can determine whether the small parts regulation was violated. Tr. at 23:4-7 (Court). Epoch Everlasting stated that is an “accurate” statement; “the Plaintiffs’ expert can say EEP violated this statute. I just think they can’t say here’s what the regulation bans.” Tr. at 23:11-16 (Biehler). Epoch Everlasting stated:

In other words, I do not believe that Mohorovic and Brickman can testify that EEP violated federal law by selling a banned product. They can say, I don’t believe under the facts of this case that EEP intended to sell these is to children age 3 and up. We don’t believe that the intent of the company and we don’t believe that these factors that we analyze in the age grading process, we don’t think they get there. We think that they violated the statute because they didn’t intend. Because that is a factual issue. What is the intent or not. They’re not interpreting the statute when they say in our opinion EEP did not intend to sell to [children] age three [and]

below, not three [and] up to younger kids. They get to say that. But I just don't think the distinction is they don't get to say EEP violated federal law based upon our interpretation

Tr. at 23:16-24:15 (Biehler). The Court summarized:

I will need to . . . give the jury the instruction on the negligence per se count, but it does seem, and I think that your conceding this, that after . . . I . . . say this is [how the regulation is interpreted], . . . then the expert . . . can't testify to the jury inconsistent with that. But after that point they are free to go ahead and testify in reference to the law and testify as to whether it was violated in this case.

Tr. at 25:10-22 (Court). Epoch Everlasting stated it agreed with the Court's statement. See Tr. at 25:23 (Biehler). The Plaintiffs also agreed to what the Court stated. See Tr. at 26:2-18 (Kaufman).

Turning to the MSJ, the Plaintiffs argued that flocked toys cannot have small parts as a matter of law and that there is a fact question whether the Calico Critters Yellow Labrador Twins toy was intended for use by children under three years of age, because Epoch Everlasting's internal marketing materials show that it targeted children younger than three. See Tr. at 42:25-44:18 (Kaufman). Epoch Everlasting stated that if the Court concludes that a flocked toy is not a per se ban, then the Court should deny the MSJ, because there is a factual issue whether the toy was intended for use by children under three years of age. See Tr. at 45:3-11 (Biehler). The Court stated that it would deny the MSJ, and that Epoch Everlasting "may ultimately win on Count 3," depending on how the Court interprets the regulations, "but at least the [MSJ] should be denied pending that resolution" of its interpretation of the regulation, "because if I allow some aspect of the negligence per se to go to the jury that's what will go to the jury and that will be a factual issue." Tr. at 45:12-24 (Court).

LAW REGARDING SUMMARY JUDGMENT

Rule 56(a) of the Federal Rules of Civil Procedure states: "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "The movant bears the

initial burden of ‘show[ing] that there is an absence of evidence to support the nonmoving party’s case.’” Herrera v. Santa Fe Pub. Sch., 956 F. 2d 1191, 1221 (D.N.M. 2013)(Browning, J.)(quoting Bacchus Indus., Inc. v. Arvin Indus., Inc., 939 F.2d 887, 891 (10th Cir. 1991)(alteration in Herrera v. Santa Fe Pub. Sch.)). See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)(“Celotex”).

Before the court can rule on a party’s motion for summary judgment, the moving party must satisfy its burden of production in one of two ways: by putting evidence into the record that affirmatively disproves an element of the nonmoving party’s case, or by directing the court’s attention to the fact that the non-moving party lacks evidence on an element of its claim, “since a complete failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.” Celotex, 477 U.S. at 323-25. On those issues for which it bears the burden of proof at trial, the nonmovant “must go beyond the pleadings and designate specific facts to make a showing sufficient to establish the existence of an element essential to his case in order to survive summary judgment.” Cardoso v. Calbone, 490 F.3d 1194, 1197 (10th Cir. 2007)(internal quotations and brackets omitted).

Plustwik v. Voss of Nor. ASA, No. 2:11-CV-00757 DS, 2013 WL 1945082, at *1 (D. Utah May 9, 2013)(Sam, J.)(emphasis added). “If the *moving* party will bear the burden of persuasion at trial, that party must support its motion with credible evidence -- using any of the materials specified in Rule 56(c) -- that would entitle it to a directed verdict if not controverted at trial.” Celotex, 477 U.S. at 331 (Brennan, J., dissenting)(emphasis in original).³⁴ Once the movant meets this burden, rule 56 requires the nonmoving party to designate specific facts showing that there is a genuine issue for trial. See Celotex, 477 U.S. at 324; Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986)(“Liberty Lobby”). In American Mechanical Solutions, LLC v. Northland Piping, Inc., 184 F. 3d 1030 (D.N.M. 2016)(Browning, J.), the Court granted summary judgment for the

³⁴Although the Honorable William J. Brennan, Jr., then-Associate Justice of the Supreme Court, dissented in Celotex, this sentence is widely understood to be an accurate statement of the law. See 10A Charles Allen Wright & Arthur R. Miller, Federal Practice and Procedure § 2727, at 470 (3d ed. 1998)(“Although the Court issued a five-to-four decision, the majority and dissent both agreed as to how the summary-judgment burden of proof operates; they disagreed as to how the standard was applied to the facts of the case.”).

defendant when the plaintiff did not offer expert evidence supporting causation or proximate causation in its breach-of-contract or breach-of-the-implied-warranty-of-merchantability claims. See 184 F. 3d at 1075-78. The Court reasoned that the plaintiff could prove neither the breach-of-contract claim's causation requirement nor the breach-of-the-implied-warranty-of-merchantability claim's proximate-causation requirement with mere common knowledge, and so New Mexico law required that the plaintiff bolster its arguments with expert testimony, which the plaintiff had not provided. See 184 F. Supp. 3d at 1067, 1073, 1075, 1079. The Court determined that, without the requisite evidence, the plaintiff failed to prove "an essential element of the nonmoving party's case," rendering "all other facts immaterial." 184 F. Supp. 3d at 1075 (internal quotation marks omitted)(quoting Plustwik v. Voss of Nor. ASA, 2013 WL 1945082, at *1). Thus, if a plaintiff has the burden of proof, and the plaintiff has no competent evidence, the defendant may move, without any competent evidence itself, past the plaintiff's lack of competent evidence, and secure summary judgment. See, e.g., Celotex, 477 U.S. at 323-25 (providing that summary judgment is proper where a plaintiff lacks evidence on an essential element of its case); Am. Mech. Sols., LLC v. Northland Piping, Inc., 184 F. Supp. 3d at 1075 (granting summary judgment because plaintiff lacked evidence on causation); Morales v. E.D. Entyre & Co., 382 F. Supp. 2d 1252, 1272 (D.N.M. 2005)(Browning, J.)(granting summary judgment because plaintiff lacked competent evidence that defendants defectively manufactured an oil distributor). A conclusory assertion that the plaintiff lacks evidence is insufficient, however, to secure summary judgment; the defendant must make some evidentiary showing that the plaintiff lacks competent evidence. See Halley v. Huckaby, 902 F.3d 1136, 1143 (10th Cir. 2018)(stating that summary judgment may be warranted if the movant notes a lack of evidence for an essential element of the claim). See also 11 James Wm. Moore et al., Moore's Federal Practice § 56.40[1][b][iv], at 56-109 to -111 (3d ed. 2018).

The party opposing a motion for summary judgment must “set forth specific facts showing that there is a genuine issue for trial as to those dispositive matters for which it carries the burden of proof.” Applied Genetics Int’l, Inc. v. First Affiliated Sec., Inc., 912 F.2d 1238, 1241 (10th Cir. 1990). See Vitkus v. Beatrice Co., 11 F.3d 1535, 1539 (10th Cir. 1993)(“However, the nonmoving party may not rest on its pleadings but must set forth specific facts showing that there is a genuine issue for trial as to those dispositive matters for which it carries the burden of proof.” (internal quotation marks omitted)). Rule 56(c)(1) provides: “A party asserting that a fact . . . is genuinely disputed must support the assertion by . . . citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials” Fed. R. Civ. P. 56(c)(1)(A). It is not enough for the party opposing a properly supported motion for summary judgment to “rest on mere allegations or denials of his pleadings.” Liberty Lobby, 477 U.S. at 259. See Abercrombie v. City of Catoosa, 896 F.2d 1228, 1231 (10th Cir. 1990); Otteson v. United States, 622 F.2d 516, 519 (10th Cir. 1980)(“[O]nce a properly supported summary judgment motion is made, the opposing party may not rest on the allegations contained in his complaint, but must respond with specific facts showing the existence of a genuine factual issue to be tried.” (citation and internal quotation marks omitted)).

Nor can a party “avoid summary judgment by repeating conclusory opinions, allegations unsupported by specific facts, or speculation.” Colony Nat’l Ins. v. Omer, No. 07-2123-JAR, 2008 WL 2309005, at *1 (D. Kan. June 2, 2008)(Robinson, J.)(citing Fed. R. Civ. P. 56(e); Argo v. Blue Cross & Blue Shield of Kan., Inc., 452 F.3d 1193, 1199 (10th Cir. 2006)(McConnell, J.)). “In responding to a motion for summary judgment, ‘a party cannot rest on ignorance of facts, on

speculation, or on suspicion and may not escape summary judgment in the mere hope that something will turn up at trial.”” Colony Nat’l Ins. v. Omer, 2008 WL 2309005, at *1 (quoting Conaway v. Smith, 853 F.2d 789, 794 (10th Cir. 1988)).

To deny a motion for summary judgment, genuine factual issues must exist that “can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.” Liberty Lobby, 477 U.S. at 250. A mere “scintilla” of evidence will not avoid summary judgment. Vitkus v. Beatrice Co., 11 F.3d at 1539 (citing Liberty Lobby, 477 U.S. at 248). Rather, there must be sufficient evidence on which the fact finder could reasonably find for the nonmoving party. See Liberty Lobby, 477 U.S. at 251 (quoting Schuylkill & Dauphin Improvement Co. v. Munson, 81 U.S. (14 Wall.) 442, 448 (1871)(“Schuylkill”)); Vitkus v. Beatrice Co., 11 F.3d at 1539. “[T]here is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted.” Liberty Lobby, 477 U.S. at 249 (citations omitted). Where a rational trier of fact, considering the record as a whole, cannot find for the nonmoving party, “there is no ‘genuine issue for trial.’” Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986)(quoting First Nat’l Bank of Ariz. v. Cities Serv. Co., 391 U.S. 253, 289 (1968)).

When reviewing a motion for summary judgment, the court should keep in mind certain principles. First, the court’s role is not to weigh the evidence but to assess the threshold issue whether a genuine issue exists as to material facts requiring a trial. See Liberty Lobby, 477 U.S. at 249. Second, the ultimate standard of proof is relevant for purposes of ruling on a summary judgment, such that, when ruling on a summary judgment motion, the court must “bear in mind the actual quantum and quality of proof necessary to support liability.” Liberty Lobby, 477 U.S.

at 254. Third, the court must resolve all reasonable inferences and doubts in the nonmoving party's favor and construe all evidence in the light most favorable to the nonmoving party. See Hunt v. Cromartie, 526 U.S. 541, 550-55 (1999); Liberty Lobby, 477 U.S. at 255 ("The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." (citation omitted)). Fourth, the court cannot decide any issues of credibility. See Liberty Lobby, 477 U.S. at 255.

There are, however, limited circumstances in which the court may disregard a party's version of the facts. This doctrine developed most robustly in the qualified immunity arena. In Scott v. Harris, 550 U.S. 372 (2007), the Supreme Court of the United States of America concluded that summary judgment is appropriate where video evidence quite clearly contradicted the plaintiff's version of the facts. See 550 U.S. at 378-81. The Supreme Court explained:

At the summary judgment stage, facts must be viewed in the light most favorable to the nonmoving party only if there is a "genuine" dispute as to those facts. Fed. Rule Civ. Proc. 56(c). As we have emphasized, "[w]hen the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial.'" *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. [at] 586-587 . . . (footnote omitted). "[T]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. [at] 247-248 When opposing parties tell two different stories, one of which is blatantly contradicted by the record, so that no reasonable jury could believe it, a court should not adopt that version of the facts for purposes of ruling on a motion for summary judgment.

That was the case here with regard to the factual issue whether respondent was driving in such fashion as to endanger human life. Respondent's version of events is so utterly discredited by the record that no reasonable jury could have believed him. The Court of Appeals should not have relied on such visible fiction; it should have viewed the facts in the light depicted by the videotape.

Scott v. Harris, 550 U.S. at 380-81 (alterations in Scott v. Harris)(emphasis in Liberty Lobby).

The Tenth Circuit applied this doctrine in Thomson v. Salt Lake County, 584 F.3d 1304 (10th Cir. 2009), and explained:

[B]ecause at summary judgment we are beyond the pleading phase of the litigation, a plaintiff's version of the facts must find support in the record: more specifically, "[a]s with any motion for summary judgment, '[w]hen opposing parties tell two different stories, one of which is blatantly contradicted by the record, so that no reasonable jury could believe it, a court should not adopt that version of the facts[.]'" *York v. City of Las Cruces*, 523 F.3d 1205, 1210 (10th Cir. 2008)(quoting *Scott*, 550 U.S. at 380); *see also Estate of Larsen ex rel. Sturdivan v. Murr*, 511 F.3d 1255, 1258 (10th Cir. 2008).

Thomson v. Salt Lake Cty., 584 F.3d at 1312 (second alteration in Thomson v. Salt Lake Cty., third and fourth alterations in York v. City of Las Cruces). "The Tenth Circuit, in *Rhoads v. Miller*, [352 F. App'x 289 (10th Cir. 2009)] explained that the blatant contradictions of the record must be supported by more than other witnesses' testimony." Lymon v. Aramark Corp., 728 F. Supp. 2d 1222, 1249 (D.N.M. 2010)(Browning, J.), *aff'd*, 499 F. App'x 771 (10th Cir. 2012).

To allege a claim for relief, rule 8 of the Federal Rules of Civil Procedure requires a pleading to contain

- (1) a short and plain statement of the grounds for the court's jurisdiction, unless the court already has jurisdiction and the claim needs no new jurisdictional support;
- (2) a short and plain statement of the claim showing that the pleader is entitled to relief; and
- (3) a demand for the relief sought, which may include relief in the alternative or different types of relief.

Fed. R. Civ. P. 8. Parties may allege new claims in motions for summary judgment. *See Evans v. McDonald's Corp.*, 936 F.2d at 1090-91. When this occurs, courts treat the motion for summary judgment as a request to amend the complaint pursuant to rule 15 of the Federal Rules of Civil Procedure. *See Viernow v. Euripides Dev. Corp.*, 157 F.3d 790 n.9 (10th Cir. 1998). The Tenth Circuit has stated that "[a]s a general rule, a plaintiff should not be prevented from pursuing a valid

claim just because she did not set forth in the complaint a theory on which she could recover, provided always that a late shift in the thrust of the case will not prejudice the other party in maintaining his defense upon the merits.” Evans v. McDonald’s Corp., 936 F.2d at 1090-91 (quotation marks omitted). While the purpose of “fact pleading” is to give defendants fair notice of claims against them “without requiring the plaintiff to have every legal theory or fact developed in detail before the complaint is filed and the parties have opportunity for discovery,” plaintiffs may not “wait until the last minute to ascertain and refine the theories on which they intend to build their case.” Evans v. McDonald’s Corp., 936 F.2d at 1091.

RELEVANT LAW REGARDING EXPERT TESTIMONY

“Since the Supreme Court of the United States decided Daubert . . . , trial courts have had the responsibility to make certain that proffered experts will assist the jury in understanding the evidence and in determining the factual issues it must decide.” United States v. Gutierrez-Castro, 805 F. Supp. 2d 1218, 1224 (D.N.M. 2011)(Browning, J.). “The Court now must not only decide whether the expert is qualified to testify, but, under Daubert, whether the opinion testimony is the product of a reliable methodology.” United States v. Gutierrez-Castro, 805 F. Supp. 2d at 1224. “Daubert . . . requires a court to scrutinize the proffered expert’s reasoning to determine if that reasoning is sound.” United States v. Gutierrez-Castro, 805 F. Supp. 2d at 1224.³⁵

³⁵One of the things that consistently amazes the Court is the unwillingness of modern lawyers to tailor their briefing to the particular judge before whom they argue. The Court still gets briefings filled with citations to other district cases, even though it has written opinions more directly on point. See, e.g., United States v. Begay, 310 F. Supp. 3d 1318, 1336 (D.N.M. 2018)(Browning, J.)(party citing Caine v. Burge, No. 11 C 8996, 2013 WL 1966381, at *1 (N.D. Ill. May 10, 2013)(Durkin, J.)) to argue for admitting expert testimony); United States v. Chapman, No. CR 14-1065 JB, 2015 WL 10401776, at *3 (D.N.M. Aug. 28, 2015)(Browning, J.)(party citing First Data Corp. v. Konya, No. CIV 04-0856, 2007 WL 2116378, at *10 (D. Colo. July 20, 2007)(Kane, J.)). There is nothing wrong -- and a lot right -- with our colleagues in other states, but it mystifies the Court why lawyers continue not to research and know the judge before whom they are practicing.

1. Rule 702.

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Nowhere is the need to research the presiding judge more important than in the Daubert area. Given Daubert's and rule 702's demands, trial judges often have to write detailed opinions, with findings of fact and conclusions of law. See, e.g., Abraham v. WPX Prod. Prods., LLC, 184 F. Supp. 3d 1150 (D.N.M. 2016)(Browning, J.); United States v. Rodriguez, 125 F. Supp. 3d 1216 (D.N.M. 2015)(Browning, J.); Montoya v. Sheldon, 286 F.R.D. 602 (D.N.M. 2012). Cf. Admissibility of Scientific Evidence, SJ081 ALI-ABA 1, 21 ("Appellate courts increasingly insist that even when no Daubert hearing is held, the district court must create a sufficient record so that the basis for the admissibility decision can be reviewed."). The written opinions are a goldmine for figuring out what the trial judge is going to do with the new expert's report. Lawyers should research their judge thoroughly through Lexis and Westlaw. In the 21st century, litigants can know their judge like the hand knows the glove.

When the Court was a young associate at a large law firm after its clerkships, the Court and a co-associate, and the Court's future partner, would swing by the University of New Mexico School of Law every evening after work, alternating days, to go through a box of slip opinions by the federal judges. The lower federal judges in the early 1980s would send the opinion to the counsel of record by mail but also send a copy to the law library. The Court and the other associate would copy almost every opinion and create binders by subject matter: rule 12(b)(1), rule 32, etc. Some binders got so large that they got dividers to divide the opinions by specific judges. The Court and the other associate kept up the laborious data collection even when the Court and the other associate started their own firm. The Court and its firm would cite, quote, and discuss the opinions of the local federal judges back to them in its briefing.

If the Court went to this much travail to locate all the opinions of the judge before whom it was appearing, imagine what it thinks when it receives a brief citing, discussing, or quoting mostly other courts' opinions on topics on which the Court has written, sometimes extensively and exhaustively. In contrast to the paper world in which the Court lived in the early and mid-1980s, all an associate has to do with Lexis and Westlaw is put in the judge's name and the subject to be researched. With research by judge and topic so easy today, there is no excuse for a lawyer not to know the opinion of the judge before whom they are practicing.

Fed. R. Evid. 702.³⁶ Rule 702 thus requires the trial court to “determine whether the expert is

³⁶Rule 702’s most prominent hurdle is the sufficiency of basis. Yet the judiciary’s uncomfortableness with analyzing an opinion’s basis can be seen in the conflict in the cases. The current conflict is whether the questions of sufficiency of basis, and of application of principles and methods, are matters of weight or admissibility. Compare David E. Bernstein & Eric G. Lasker, Defending Daubert: It’s Time to Amend Federal Rule of Evidence 702, 57 Wm. & Mary L. Rev. 1, 32 (2015) (“[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, Daubert and Rule 702 mandate the exclusion of that unreliable opinion testimony.” (quoting Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 255 (2d Cir. 2005)), with Bernstein & Lasker, supra, at 33 (“[T]he soundness of the factual underpinnings of the expert’s analysis and the correctness of the expert’s conclusions based on that analysis are factual matters to be determined by the trier of fact.” (quoting Milward v. Acuity Speciality Prods. Grp. 639 F.3d 11, 22 (1st Cir. 2011))). There should not be a conflict. Rule 702 states that these are questions of admissibility. Yet many courts treat them as questions of weight. See, e.g., Bernstein & Lasker, supra, at 33 (citing several Courts of Appeals that instruct district courts to consider the sufficiency of basis and/or application of the methodology as questions of weight).

What is most interesting is what the divergence from Supreme Court precedent and rule 702 suggest. The divergence suggests that Daubert and rule 702 are too academic. Daubert and rule 702 write better than they work in the courtroom and in practice. Lower courts continue -- rightfully so -- to be uncomfortable with deciding these issues with the Sixth and Seventh Amendments to the Constitution of the United States protecting the right to jury trials in civil and criminal cases. Cf. Bernstein & Lasker, supra, at 33 (2015) (“[C]ourts have held that ‘[t]he district court usurps the role of the jury, and therefore abuses its discretion, if it unduly scrutinizes the quality of the expert’s data and conclusions rather than the reliability of the methodology the expert employed.’” (quoting Manpower, Inc. v. Ins. of Pa., 732 F.3d 796, 806 (7th Cir.)); Ronald J. Allen, Esfand Fafisi, Daubert and its Discontents, Brooklyn L.R., 131, 147 (2010) (describing an argument for Daubert’s unconstitutionality under the Seventh Amendment).

The Court is concerned that the federal courts will overact to the wayward opinions that have created a split whether sufficiency of basis and application of methods is for the court or goes to the evidence’s weight. The Court is concerned that the federal courts are going in the direction of new rules. There is thus a built-in institutional bias towards more rules and amendments. The Judicial Conference runs the federal judiciary through committees. See About the Judicial Conference, U.S. Cts., <https://www.uscourts.gov/about-federal-courts/governance-judicial-conference/about-judicial-conference> (last visited Jan. 5, 2019) (“The Conference operates through a network of committees . . .”). The Judicial Conference has a Standing Committee on Rules. The Standing Committee has five Advisory Committees: (i) Civil Procedure; (ii) Criminal Procedure; (iii) Evidence; (iv) Bankruptcy; and (v) Appellate. See How the Rulemaking Process Works, U.S. Cts., <https://www.uscourts.gov/rules-policies/about-rulemaking-process/how-rulemaking-process-works> (last visited Jan. 5, 2019). Each of these advisory committees has a reporter, almost always a prominent professor. See Overview for the Bench, Bar, and Public, U.S. Cts., <https://www.uscourts.gov/rules-policies/about-rulemaking-process/how-rulemaking-process-works/overview-bench-bar-and-public> (last visited Jan. 5, 2019). The reporter position is more prestigious if the reporter can get new rules promulgated. They have to justify their

proposing to testify to (1) scientific, technical, or other specialized knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.” United States v. Muldrow, 19 F.3d 1332, 1337 (10th Cir. 1994). Rule 702 uses a liberal definition of “expert.” Fed. R. Evid. 702 advisory committee’s note to 1972 proposed rules (“[W]ithin the scope of this rule are not only experts in the strictest sense of the word, e.g., physicians, physicists, and architects, but also the large group sometimes called ‘skilled’ witnesses, such as bankers or landowners testifying to land values.”). An expert is “required to possess such skill, experience or knowledge in that particular field as to make it appear that his opinion would rest on substantial foundation and would tend to aid the trier of fact in his search for truth.” LifeWise Master Funding v. Telebank, 374 F.3d 917, 928 (10th Cir. 2004). See United States v. Harry, 20 F. Supp. 3d 1196, 1243 (D.N.M. 2014)(Browning, J.)(deeming inadmissible testimony on a sex crime’s victim’s demeanor during an examination, because “demeanor is not always a reliable indicator whether someone is telling the truth, especially about sex -- then no expert testimony is needed. That knowledge is well within the knowledge of jurors and most people.”); United States v. Rodella, No. CR 14-2783 JB, 2014 WL 6634310, at *25 (D.N.M. Nov. 19, 2014)(Browning, J.)(stating that “testimony regarding nationally accepted police standards is irrelevant” to issues of “excessive force and” reasonableness). The proponent of expert testimony has the burden of establishing by a

existence. There is thus a very smart, likeable, and well-liked person putting pressure on the committee to amend the rules. While judges are more conservative about promulgating new rules, they too often succumb to the reporter’s pressure. The result is that the federal judiciary and the bar gets a host of new rules almost every year. The development of new rules burdens the federal judiciary and the bar -- all of which are overworked -- with mandatory changes each year, often constituting little more than stylistic changes. Everyone has to get new rule books every year. The burden of new rules often does not justify the meager benefits of the changes.

preponderance of the evidence that the pertinent admissibility requirements are met.³⁷ See Morales v. E.D. Etnyre & Co., 382 F. Supp. 2d 1252, 1266 (D.N.M. 2005)(Browning, J.)(citing Bourjaily v. United States, 483 U.S. 171, 175 (1987)). Once the trial court has determined that expert testimony would be helpful to the trier of fact, a witness “may qualify as an expert by knowledge, skill, experience, training, or education and . . . the expert . . . should not be required to satisfy an overly narrow test of his own qualifications.” Gardner v. Gen. Motors Corp., 507 F.2d 525, 528 (10th Cir. 1974)(internal quotation marks omitted). See United States v. Rodella, 2014 WL 6634310, at *20 (“Because of [the proposed expert’s] lack of practical experience, lack of nationwide experience, and lack of an advanced degree in criminology or law enforcement, [the proposed expert’s] is not qualified to testify about nationally accepted police procedures and practices.”); United States v. Goxcon-Chagal, 886 F. Supp. 2d at 1245 (determining an expert qualified to testify to drug trafficking when he had personal knowledge of the subject from working in the Drug Enforcement Agency for almost

³⁷The Court is clipping the wings of experts all the time. See, e.g., Abraham v. WPX Prod. Prods., LLC, 184 F. Supp. 3d at 1204 (precluding an expert from discussing class certification requirements, but allowing the expert to testify to information about royalty instruments); United States v. Rodriguez, 125 F. Supp. 3d at 1255-56 (permitting an expert to describe a cartel’s structure and organization, and to explain drug running, but not admitting the expert’s testimony opining that the defendant was running drugs); Montoya v. Sheldon, 286 F.R.D. at 619 (precluding a treating physician from testifying about a party’s PTSD diagnosis, opinions about the causes for a party’s symptoms, or a party’s prognosis). Attorneys ask experts to do too much, and experts try to do too much. The experts are being paid; they are trying to be helpful to the attorney. Cf. Mark I. Bernstein, Jury Evaluation of Expert Testimony Under the Federal Rules, Drexel L. Rev. 239, 268 (2015)(“Any use of expert witnesses paid by a party raises concerns of partisanship, competency, and honesty. Because experts are partisan witnesses paid by a party, there is an inevitable danger of bias.”). The experts will often do anything. They toss statements into their reports to be helpful. Too many attorneys release the report as written -- without editing and without trimming. This failure to edit and to trim creates unnecessary litigation. Many expert reports contain statements that the proponent attorney does not need or even want. The reports draw Daubert motions or rule 702 challenges. The proponent is then forced to defend the statements that he or she does not even need or want.

fifteen years).

Courts should, under the Federal Rules of Evidence, liberally admit expert testimony, see United States v. Gomez, 67 F.3d 1515, 1526 (10th Cir. 1995)(describing rule 702 as a “liberal standard”), and the trial court has broad discretion in deciding whether to admit or exclude expert testimony, see Werth v. Makita Elec. Works, Ltd., 950 F.2d 643, 647 (10th Cir. 1991)(noting the trial court’s decision will not be overturned “unless it is manifestly erroneous or an abuse of discretion”). “The Tenth Circuit appears to draw a line between expert testimony regarding credibility and expert testimony regarding voluntariness.” United States v. Ganadonegro, 805 F. Supp. 2d 1188, 1214 (D.N.M. 2011)(Browning, J.)(citing United States v. Benally, 541 F.3d 990, 996 (10th Cir. 2008)). “The Tenth Circuit may draw this distinction because, generally, it is the jury’s exclusive function to make credibility determinations . . . whereas a court makes a pretrial determination of the constitutional voluntariness of a statement.” United States v. Ganadonegro, 805 F. Supp. 2d at 1214 (citation omitted)(citing United States v. Adams, 271 F.3d 1236, 1245 (10th Cir. 2001)).

2. The Standard in Daubert.

In its gatekeeper role, a court must assess the reasoning and methodology underlying an expert’s opinion, and determine whether it is both scientifically valid and relevant to the facts of the case, *i.e.*, whether it is helpful to the trier of fact. See Daubert, 509 U.S. at 594-95; Witherspoon v. Navajo Ref. Co., No. 03-1160, 2005 WL 5988649, at *2 (D.N.M. July 18, 2005)(Black, J.)(citing Dodge v. Cotter Corp., 328 F.3d 1212, 1221 (10th Cir. 2003)).³⁸ The

³⁸The current law -- and its trajectory -- are casting serious shadows over using expensive experts. This is particularly true in cases involving jury trials. It is probably a good time for the judiciary to rethink expert testimony rather than continuing with the current regime and making incremental changes.

Supreme Court articulated a non-exclusive list of factors that weigh into a district court's first-step reliability determination, including: (i) whether the method has been tested; (ii) whether the method has been published and subject to peer review; (iii) the error rate; (iv) the existence of standards and whether the witness applied them in the present case; and (v) whether the witness'

Lawyers and appellate courts overemphasize the importance of experts, and distrust juries. See Sanja Kutnjak Ivkovic & Valerie P. Hans, Jurors' Evaluations of Expert Testimony: Judging the Messenger and the Message, 28 Law & Soc. Inquiry 441, 442 (2003) ("One key assumption underlying the Daubert line of cases is that jurors might be duped by a persuasive but untrustworthy expert who testifies about matters that are not based on sound scientific principles or data."). Cf., Elaine E. Sutherland, Undue Deference to Experts Syndrome?, 16 Ind. Int'l & Comp. L. Rev. 375, 382 (2006) ("After all, if one is coming from a position of ignorance, the person who holds the key to that certain body of knowledge is something of a savior. The danger for the legal system is that this empowerment of the expert witness will result in undue deference to his or her opinion."). Appellate judges often do not have extensive or any trial experience, particularly as Presidents want to rule from the grave, and appoint younger and younger appellate judges, who often -- because of their years -- have not spent a lot of time trying cases in the courtroom before juries. Academics, corporate lawyers, general counsel, and appellate judges -- without considerable courtroom experience -- think that experts will easily mislead juries. Yet, the Court talks regularly to juries after jury trials, and the Court listens to trial lawyers talking to juries after jury trials. Juries often expressly state that they disregarded the parties' experts. The Court often hears comments like the "expert arrogant and/or incomprehensible."

Part of the problem is that academics and, often, appellate jurists do not appreciate or understand modern American jurors. Jurors have become very independent, and do not take direction well or easily from anyone -- the judge, lawyers, or experts. The days of dressing up for court in coats and ties, and doing what the judge tells them to do are fading. Jurors question everything. If the Court tells them to go in one door, they want to use another. Whereas jurors used to complement the Court's jury instructions as giving a roadmap to the jurors' decisions, jurors now criticize even the uniform or pattern jury instructions. Modern American jurors do not like to think that they are being told what to do. And they certainly do not like experts telling them what to do; modern American jurors do not like the idea of "experts" who are smarter than they are.

At the same time that modern American jurors are showing more independence, paternalistic Daubert hearings have proliferated. This phenomenon raises many concerns. One concern is the sheer prevalence of Daubert motions. Cf. Cynthia Lynne Pike, The Impact of Revised MRE 702 and 703 in Response to Daubert, 52 Wayne L. Rev. 285, 301 (2006) (describing the effects of a state-specific rule resembling rule 702 and stating, "One of the more important tactical strategies in dealing with the court's role as gatekeeper under the new MRE 702 is the use of motions in limine and other pretrial evidentiary hearings."). Motions to dismiss, class certification motions, and motions for summary judgment, sentencings, competency hearings -- in addition to testimony -- require Daubert hearings. The costs of Daubert motions, to the court and the parties, is staggering. The time-consuming nature of Daubert motions is overwhelming.

method is generally accepted as reliable in the relevant medical and scientific community.³⁹ See Daubert, 509 U.S. at 594-95. The court is also to consider whether the witness' conclusion represents an "unfounded extrapolation" from the data; whether the witness has adequately accounted for alternative explanations for the effect at issue; whether the opinion was reached for the purposes of litigation or as the result of independent studies; or whether it unduly relies on anecdotal evidence. See Witherspoon v. Navajo Ref. Co., 2005 WL 5988649, at *3 (citing Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)). The Tenth Circuit stated the applicable standard in Norris v. Baxter Healthcare Corp., 397 F.3d 878 (10th Cir. 2005):

Rule 702 requires the district court to "ensure that any and all scientific testimony or evidence is not only relevant, but reliable." Bitler v. A.O. Smith Corp., 391 F.3d 1114, 1120 (10th Cir. 2004)(quoting Daubert, 509 U.S. at 589 . . .). This obligation involves a two-part inquiry. Id. "[A] district court must [first] determine if the expert's proffered testimony . . . has 'a reliable basis in the knowledge and experience of his [or her] discipline.'" Id. (quoting Daubert, 509 U.S. at 592 . . .). In making this determination, the district court must decide "whether the reasoning or methodology underlying the testimony is scientifically valid. . . ." Id. (quoting Daubert, 509 U.S. at 592-93 . . .). Second, the district court must further inquire into whether proposed testimony is sufficiently "relevant to the task at hand." Daubert, 509 U.S. at 597

Norris v. Baxter Healthcare Corp., 397 F.3d at 883-84 (footnote omitted). "The second inquiry is related to the first. Under the relevance prong of the Daubert analysis, the court must ensure that the proposed expert testimony logically advances a material aspect of the case. . . . The evidence must have a valid scientific connection to the disputed facts in the case." Norris v. Baxter Healthcare Corp., 397 F.3d at 884 n.2 (citing Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1315 (9th Cir. 1995)(on remand from the Supreme Court); Daubert, 509 U.S. at 591). If the

³⁹Federal courts are obsessed with reliability problems. This idea pops up several places and in several ways, creating multiple grounds upon which the court has the power to exclude the expert. See Admissibility of Scientific Evidence, SJ081 ALI-ABA 1, 27 (noting that courts treat the "assist the trier of fact" requirement for expert testimony as a relevancy requirement, and stating that rule 401 already requires evidence to be relevant).

expert's proffered testimony fails on the first prong, the court does not reach the second prong. See Norris v. Baxter Healthcare Corp., 397 F.3d at 884. In Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), the Supreme Court expanded the rules under Daubert to non-scientific expert testimony. See Kumho Tire Co. v. Carmichael, 526 U.S. at 141 ("We conclude that Daubert's general holding -- setting forth the trial judge's general 'gatekeeping' obligation -- applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." (quoting Carmichael v. Samyang Tires, Inc., 923 F. Supp. 1514, 1521 (S.D. Ala. 1996))). The Supreme Court recognized in Kumho Tire Co. v. Carmichael that the factors from Daubert will not apply to all cases:

Our emphasis on the word "may" thus reflects Daubert's description of the Rule 702 inquiry as a flexible one. Daubert makes clear that the factors it mentions do not constitute a definitive checklist or test. And Daubert adds that the gatekeeping inquiry must be tied to the facts of a particular case.

Kumho Tire Co. v. Carmichael, 526 U.S. at 150 (internal quotation marks omitted).

In conducting its review under Daubert, a court must focus generally on "principles and methodologies, and not on the conclusions generated." Armeanu v. Bridgestone/Firestone N. Am., Tire, LLC, No. CIV 05-0619, 2006 WL 4060665, at *11 (D.N.M. Sept. 26, 2006)(Browning, J.)(citing Daubert, 509 U.S. at 595). "Despite this focus on methodology, an expert's conclusions are not immune from scrutiny . . . and the court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." Armeanu v. Bridgestone/Firestone N. Am., Tire, LLC, 2006 WL 4060665, at *11 (alterations and internal quotation marks omitted)(quoting Dodge v. Cotter Corp., 328 F.3d at 1222). The proponent of the expert's opinion testimony bears the burden of establishing that the expert is qualified, that the methodology he or she uses to support his or her opinions is reliable, and that his or her opinion fits the facts of the case and thus will be helpful to the jury. See Norris v. Baxter Healthcare Corp.,

397 F.3d at 881. The Tenth Circuit noted in Hollander v. Sandoz Pharm. Corp., 289 F.3d 1193 (10th Cir. 2002):

Because the district court has discretion to consider a variety of factors in assessing reliability under Daubert, and because, in light of that discretion, there is not an extensive body of appellate case law defining the criteria for assessing scientific reliability, we are limited to determining whether the district court's application of the Daubert manifests a clear error of judgment or exceeds the bounds of permissible choice in the circumstances. . . . Thus, when coupled with this deferential standard of review, Daubert's effort to safeguard the reliability of science in the courtroom may produce a counter-intuitive effect: different courts relying on the essentially the same science may reach different results.

289 F.3d at 1206. The United States Court of Appeals for the Ninth Circuit noted in Claar v. Burlington N.R.R., 29 F.3d 499 (9th Cir. 1994):

Coming to a firm conclusion first and then doing research to support it is the antithesis of this method. Certainly, scientists may form initial tentative hypotheses. However, scientists whose conviction about the ultimate conclusion of their research is so firm that they are willing to aver under oath that it is correct prior to performing the necessary validating tests could properly be viewed by the district court as lacking the objectivity that is the hallmark of the scientific method.

29 F.3d at 502-03.

Once reliability is established, however, it is still within the district court's discretion to determine whether expert testimony will be helpful to the trier of fact. In making that determination, the court should consider, among other factors, the testimony's relevance, the jurors' common knowledge and experience, and whether the expert's testimony may usurp the jury's primary role as the evaluator of evidence.

Ram v. N.M. Dep't of Env't, No. CIV 05-1083, 2006 WL 4079623, at *10 (Dec. 15, 2006)(Browning, J.)(citing United States v. Rodriguez-Felix, 450 F.3d 1117, 1123 (10th Cir. 2006)).

An untested hypothesis does not provide a scientific basis to support an expert opinion. See Norris v. Baxter Healthcare Corp., 397 F.3d at 887 (“[A]t best, silicone-associated connective tissue disease is an untested hypothesis. At worst, the link has been tested and found to be

untenable. Therefore, there is no scientific basis for any expert testimony as to its specific presence in Plaintiff.”); In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1228 (D. Colo. 1998)(Sparr, J.) (“An untested hypothesis cannot be a scientifically reliable basis for an opinion on causation.”). A court is not required “to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert. The court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” Gen. Elec. Co. v. Joiner, 522 U.S. at 146. See Hollander v. Sandoz Pharm. Corp., 289 F.3d at 1209 (noting a lack of similarity between animal studies and human studies); Tyler v. Sterling Drug, Inc., 19 F. Supp. 2d 1239, 1244 (N.D. Okla. 1998)(Cook, J.) (“Test results on animals are not necessarily reliable evidence of the same reaction in humans.”). Courts have excluded experts’ opinions when the experts depart from their own established standards. See Truck Ins. Exch. v. MagneTek, Inc., 360 F.3d 1206, 1213 (10th Cir. 2004) (“The district court noted that [the expert]’s opinion did not meet the standards of fire investigation [the expert] himself professed he adhered to.”); Magdaleno v. Burlington N.R.R., 5 F. Supp. 2d 899, 905 (D. Colo. 1998)(Babcock, J.) (“In sum, [the expert]’s methodology is not consistent with the methodologies described by the authors and experts whom [the expert] identifies as key authorities in his field.”).

3. Necessity of Evaluating an Issue Under Daubert.

The restrictions in Daubert apply to both “novel” expert testimony and “well-established propositions.” 509 U.S. at 593 n.11 (“Although the *Frye*^[40] decision itself focused exclusively on ‘novel’ scientific techniques, we do not read the requirements of Rule 702 to apply specially or

⁴⁰Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), superseded by rule 702 of the Federal Rules of Evidence, held that, for an expert opinion to be admissible, “the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.” 293 F. at 1014.

exclusively to unconventional evidence.”). “Of course, well-established propositions are less likely to be challenged than those that are novel, and they are more handily defended.” Daubert, 509 U.S. at 593 n.11. “Indeed, theories that are so firmly established as to have attained the status of scientific law, such as the laws of thermodynamics, properly are subject to judicial notice under Federal Rule of Evidence 201.” Daubert, 509 U.S. at 593 n.11.

“[W]hen experts employ established methods in their usual manner, a district court need not take issue under Daubert. . . .” Att’y Gen. of Okla. v. Tyson Foods, Inc., 565 F.3d 769, 780 (10th Cir. 2009). “[H]owever, where established methods are employed in new ways, a district court may require further indications of reliability.” Att’y Gen. of Okla. v. Tyson Foods, Inc., 565 F.3d at 780. Whether courts have accepted theories underlying an expert’s opinion is a relevant consideration in determining whether expert testimony is reliable. See Att’y Gen. of Okla. v. Tyson Foods, Inc., 565 F.3d at 780 (“The case law indicates that the courts are not unfamiliar with the PCR methodology,^[41] and in fact some courts have indicated their acceptance of it.”).⁴²

⁴¹PCR, a “[p]olymerase chain reaction,” Att’y Gen. of Okla. v. Tyson Foods, Inc., 565 F.3d at 780, is a widely used method for copying DNA segments. Polymerase Chain Reaction, Wikipedia, https://en.wikipedia.org/wiki/Polymerase_chain_reaction (last visited Nov. 28, 2018).

⁴²Much of the focus of current debate about experts is on forensic evidence, which comes in many forms. The challenge to forensic evidence comes from two areas: (i) the federal courts; and (ii) the scientific community. The reports of the National Academies of Science (“NAS”) and the President’s Council of Advisors on Science and Technology (“PCAST”) raise challenges to the reliability of forensic methods. See Executive Office of the President President’s Council of Advisors on Science and Technology, Report to the President, Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature-Comparison Methods (Sept. 2016); Committee on Identifying the Needs of the Forensic Sciences Community, National Research Council, Strengthening Forensics Science in the United States: A Path Forward (July 2009). There is increasing skepticism of the legal profession’s most cherished evidence, including fingerprints, DNA, firearms, and breath tests. See, e.g., President’s Council of Advisors on Science and Technology, supra, at 67-110; Committee on Identifying the Needs of the Forensic Sciences Community, supra, at 42-48.

The Court is concerned that the federal judiciary is moving toward a freestanding rule on forensic evidence. The Court is not a big fan of addressing the topic of forensic evidence through rulemaking. No rule, procedures manual, or note is needed to tell judges that there is no certainty

LAW REGARDING EXPERT TESTIMONY ON ULTIMATE ISSUES

Rule 704 of the Federal Rules of Evidence states:

- (a) **In General -- Not Automatically Objectionable.** An opinion is not objectionable just because it embraces an ultimate issue.
- (b) **Exception.** In a criminal case, an expert witness must not state an opinion about whether the defendant did or did not have a mental state or condition that constitutes an element of the crime charged or of a defense. Those matters are for the trier of fact alone.

with forensic opinions. There is also no reasonable degree of certainty. These opinions are now considered overstated: in the old days -- like last week -- attorneys would routinely ask: "Doctor, in your opinion, to a reasonable degree of certainty, that the plaintiff's appendix was on the left side of the body?"

The nation does not need another rule. An examination of Article VII -- Opinions and Expert Testimony -- shows six rules: (i) rule 701 -- Opinion Testimony by Lay Witnesses; (ii) rule 702 -- Testimony by Expert Witnesses; (iii) rule 703 -- Bases of an Expert's Opinion Testimony; (iv) rule 704 -- Opinion on an Ultimate Issue; (v) rule 705 -- Disclosing the Facts or Data Underlying an Expert's Opinion; (vi) rule 706 -- Court-Appointed Expert Witnesses (a bad idea in about all cases). See Fed. R. Evid. 701-06. If the reporter would drop rule 706, perhaps there would be room for a rule pertaining to forensic evidence.

The Court is concerned with what a new rule would look like. The judiciary could make its point in a committee note, but without a new rule, there is no need for a new note. The PCAST report does not propose a change to the Evidence Rules. Rather, PCAST proposes a best procedures manual. See President's Council of Advisors on Science and Technology, supra, at 145. It would be better if legal leaders do like Duke University School of Law has done for class actions and the Sedona Conference has done for electronic discovery. See Class-Action Settlement Conference, Duke Law, <https://law.duke.edu/judicialstudies/conferences/oct2016/> (last visited Jan. 7, 2019); The Sedona Conference Working Group Series, The Sedona Conference, <https://thesedonaconference.org/wgs> (last visited Jan. 7, 2019). Rather than a new rule or note, the Court believes that a best practices manual -- prepared by professional leaders that come together to write -- and not the judiciary -- would be the better approach.

The Court expects several difficulties with a new rule. The first difficulty with any rule on forensic evidence will be determining to whom it should apply. A new rule would presumably apply to forensic witnesses' testimony. Such witnesses include people testifying about evidence about through scientific means, by comparing patterns, or by "experimental or scientific analysis." See Evidence, Black's Law Dictionary (10th ed. 2014). After the Court and the bar have identified the universe of experts to whom the rule applies or the best practices apply, the new rules' requirements must be determined. An expert must already satisfy all of rule 702's requirements. Under a new rule, the expert will also need to satisfy all of the new requirements. With more handles, the chances of exclusion or limiting are enhanced. Rule 702's requirements, however, are enough, and the law should not require more.

Fed. R. Evid. 704. “Traditionally, there was a general doctrine that witnesses could not give their opinion or conclusions on an ultimate issue of fact.” Vondrak v. City of Las Cruces, No. CIV 05-0172 JB/LAM, 2009 WL 3241555, at *10 (D.N.M. Aug. 25, 2009)(Browning, J.). “The stated justification was sometimes that such testimony usurps the function or invades the province of the jury.” Vondrak v. City of Las Cruces, 2009 WL 3241555, at *10 (quoting 1 K. Broun, McCormick on Evidence § 12 (6th ed. 2006 update)). The Federal Rules of Evidence reflect that the ultimate-issue rule has been abolished. See United States v. Smith, 156 F.3d 1046, 1054 (10th Cir. 1998). Although rule 704(a) permits an expert to testify about areas that embrace an ultimate issue, there are some other limitations, aside from those that rule 704(b) expressed, regarding testimony on ultimate issues. More specifically, the Tenth Circuit has stated that ““a expert may not state legal conclusions drawn by applying the law to the facts.”” United States v. Bedford, 536 F.3d 1148, 1158 (10th Cir. 2008)(quoting A.E. by and Through Evans v. Indep. Sch. Dist. No. 25, of Adair Cty., 936 F.2d 472, 476 (10th Cir. 1991)).

“Rule 704(b) prohibits an expert from expressly stating the final conclusion or inference as to a defendant’s mental state; it does not prevent an expert from testifying to facts or opinions from which the jury could conclude or infer that the defendant had the requisite mental state.” United States v. Ganadonegro, No. CR 09-0312 JB, 2012 WL 592170, at *5 (D.N.M. Feb. 17, 2012)(Browning, J.)(citing United States v. Torres, 53 F.3d 1129, 1141-42 (10th Cir. 1995)). The restrictions in rule 704(b) do not apply to lay witnesses, see United States v. Goodman, 633 F.3d 963, 968 (10th Cir. 2011), although the lay witnesses’ testimony must still be helpful to the trier of fact to satisfy rule 701, see Fed. R. Evid. 701(b). “[Rules 701, 702, and 403] afford ample assurances against the admission of opinions [under rule 704] which would merely tell the jury what result to reach, somewhat in the manner of the oath-helpers of an earlier day.” United States

v. Barile, 286 F.3d 749, 759-60 (4th Cir. 2002). Pursuant to rule 704, it is the Court’s task “to distinguish [helpful] opinion testimony that embraces an ultimate fact from [unhelpful] opinion testimony that states a legal conclusion.” United States v. Perkins, 470 F.3d 150, 158 (4th Cir. 2006)(internal quotation marks omitted)(quoting United States v. Barile, 286 F.3d at 760). In making that determination, a court should consider whether the question tracks the language of the legal principle or statute at issue, and then consider whether any terms employed have a specialized legal meaning. See United States v. Perkins, 470 F.3d at 158. The Court has addressed this issue in various contexts. See, e.g., Sec’y & Exch. Comm’n v. Goldstone, No. CIV 12-0257 JB/LFG, 2016 WL 3135651, at *1, *44 (D.N.M. May 10, 2016)(Browning, J.)(internal quotation marks omitted)(prohibiting, in a case involving a Form 10-K’s allegedly “fraudulent misrepresentations and omissions,” expert testimony on whether the defendants’ actions were “reasonable” or “certain information” disclosed was “material” and distinguishing the case from Tenth Circuit decisions in which “[t]he issues . . . were far simpler and subject to easy determination by a single expert”); United States v. Rodella, 2014 WL 6634310, at *29 (rejecting expert testimony as on an ultimate issue when the United States introduced the expert to testify to whether an officer “acted reasonably or violated the Constitution”); United States v. Gould, No. CR 03-2274 JB, 2007 WL 1302596, at *4 (D.N.M. March 17, 2007)(Browning, J.)(“The Tenth Circuit has indicated in recent opinions that, in the 42 U.S.C. § 1983 context, the jury cannot use law enforcement policies and standards to inform the debate whether a civil rights violation has occurred” (citing Tanberg v. Sholtis, 401 F.3d 1151, 1163-64 (10th Cir. 2005)); Marquez v. City of Albuquerque, 399 F.3d 1216, 1222 (10th Cir. 2005); Chamberlin v. City of Albuquerque, No. CIV 02-0603, 2005 WL 2313527 (D.N.M. July 31, 2005)(Browning, J.).

NEW MEXICO LAW REGARDING NEGLIGENCE PER SE

To establish a negligence per se claim, a plaintiff must prove: (i) that there is a statute

which prescribes certain actions or defines a standard of conduct, either explicitly or implicitly; (ii) that the defendant violated the statute; (iii) that the plaintiff must be in the class of persons which the statute seeks to protect; and (iv) that the harm or injury to the plaintiff must generally be that which the Legislature, through the statute, sought to prevent. See Rimbart v. Eli Lilly & Co., 577 F. Supp. 2d 1174, 1204 (D.N.M. 2008)(Browning, J.)(citing Johnstone v. City of Albuquerque, 2006-NMCA-119, ¶ 16, 145 P.3d 76, 82⁴³). To hold a defendant liable under a claim of negligence per se, the plaintiff must show that the defendant violated a specific statute. See Parker v. E. I. DuPont deNemours & Co., 1995-NMCA-086, ¶ 40, 909 P.2d 1, 12. New Mexico Uniform Civil Jury Instruction UJI 13-1501 provides:

There [was a] [were] statute[s] in force in this state, at the time of the occurrence in question, which provided that:

(Quote or paraphrase the applicable part of the statute in question. If more than one statute is in question, list each statute separately)

If you find from the evidence that _____ (party) violated [this] [any one of these] statute[s], then _____'s conduct constitutes negligence as a matter of law, [unless you further find that such violation was excusable or justified].

[To legally justify or excuse a violation of a statute, the violator must sustain the burden of showing that [s]he did that which might reasonably be expected of a person of ordinary prudence, acting under similar circumstances, who desired to comply with the law.]

N.M.R.A. Civ. UJI 13-1501. This instruction appears in Chapter Fifteen, Statutes and Ordinances, and not in Chapter Sixteen, Tort Law -- Negligence. The "Directions for Use" for UJI 13-1501

⁴³The Court is confident that, if presented with the issue, the Supreme Court of New Mexico would agree with the Court of Appeals of New Mexico's statement in Johnstone v. City of Albuquerque, 2006-NMCA-119, ¶ 16, 145 P.3d at 82, of the elements required for a negligence per se claim under New Mexico law, based on the Supreme Court of New Mexico's decision in Archibeque v. Homrich, 1975-NMSC-066, 542 P.2d 820, in which the Supreme Court of New Mexico recited the same test for negligence per se in New Mexico. 1975-NMSC-066, ¶ 15, 542 P.2d at 825.

notes that “UJI 13-1503 should be used in addition to this instruction when there is an issue of proximate cause.” N.M.R.A., Civ. UJI 13-1501, Directions for Use. N.M.R.A., Civ. UJI 13-1503 provides:

Negligence resulting from a violation of a[n] [statute] [or] [ordinance] is no different in effect from that resulting from other acts or omissions constituting negligence. In each case the negligence is of no consequence unless it was a cause of or contributed to, an injury found by you to have been suffered by the plaintiff.

N.M.R.A. Civ. UJI 13-1503.

**LAW REGARDING THE FEDERAL HAZARDOUS SUBSTANCES ACT AND THE
SMALL PARTS REGULATION 16 C.F.R. § 1500.18(a)(9)**

The Federal Hazardous Substances Act, 15 U.S.C. §§ 1261-74 (“FHSA”), prohibits the “introduction or delivery for introduction into interstate commerce of any misbranded hazardous substance or banned hazardous substance.” 15 U.S.C. § 1263(a). Under the FHSA, the term “hazardous substances” includes substances which are toxic, corrosive, irritants, strong sensitizers, flammable, combustible, or radioactive, as well as “any toy or other article intended for use by children” which the Consumer Products Safety Commission (“CPSC” or the “Commission”), an independent federal agency which administers the FHSA,⁴⁴ “determines by regulation” presents an “electrical, mechanical, or thermal hazard.” 15 U.S.C. § 1261(f)(1)(D). The term “mechanical hazard” includes any article that “if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness . . . because the article (or any part or accessory thereof) may be aspirated or ingested”

⁴⁴In the Consumer Product Safety Act, 15 U.S.C. §§ 2051-89 (“CPSA”), Congress established an independent federal agency, the CPSC, to administer the FHSA. 15 U.S.C. § 2053; 15 U.S.C. § 1261(f)(1)(D). See also 15 U.S.C. § 1269(a) (authorizing the CPSC to issue regulations). See 16 C.F.R. § 1500.18 (“[b]ann[ing] toys and other . . . articles intended for use by children” that are hazardous); 16 C.F.R. § 1500.1 (“[T]he regulations of the Consumer Product Safety Commission [are] issued pursuant to and for the implementation of the Federal Hazardous Substances Act”).

15 U.S.C. § 1261(s)(7).

The FHSA provides:

The term “banned hazardous substance” means (A) any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted; or (B) any hazardous substance intended, or packaged in a form suitable, for use in the household, which the [CPSC] by regulation classifies as a “banned hazardous substance” on the basis of a finding that, notwithstanding such cautionary labeling as is or may be required under this Act for that substance, the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce: Provided, That the [CPSC], by regulation . . . (ii) shall exempt from clause (A), and provide for the labeling of, common fireworks . . . to the extent that [it] determines that such articles can be adequately labeled to protect the purchasers and users thereof.

15 U.S.C. § 1261(q)(1). The Tenth Circuit has not addressed the scope of the FHSA, but the United States Court of Appeals for the Eighth Circuit explains how the two § 1261(q)(1) clauses function:

[I]t is clear from the plain language of the statute that Congress intended Clause A and Clause B to serve two different purposes. Clause A, on its face and through subsection (ii) of the proviso, expressly bans hazardous products that are intended solely for use by children unless those products can be adequately labeled. Therefore, any hazardous products that are not intended solely for use by children, and products that are adequately labeled, are not governed by Clause A. That does not mean that such hazardous products are immune from the jurisdiction of the CPSC -- only that they cannot be banned pursuant to that particular clause. Clause B serves the more general purpose of banning hazardous substances regardless of whether they are intended for children or adults, and “notwithstanding . . . cautionary labeling.” 15 U.S.C. § 1261(q)(1)(B). The clauses do not conflict with one another . . . ; rather, the clauses complement one another.

Clause B does not provide a list of banned products. Instead, the clause requires the CPSC to develop rules governing the banning of hazardous substances,

Shelton v. Consumer Prod. Safety Comm’n, 277 F.3d 998, 1005 (8th Cir. 2002). See Toy Mfrs. of Am., Inc. v. Blumenthal, 806 F. Supp. 336, 339 (D. Conn. 1992)(Burns, J.) (“If a toy or other

article intended for use by children is found to be a hazardous substance, the statute commands that it be banned completely from interstate commerce; no amount of labeling can make it safe.”)(citing 15 U.S.C. § 1261(q)(1)), aff’d, 986 F.2d 615 (2d Cir. 1992).

The CPSC has the power to: (i) declare a product to be a hazardous substance, 15 U.S.C. § 1262(a)(1); (ii) require labeling in addition to that required by the statutes, 15 U.S.C. § 1262(b); (iii) exempt substances from the full requirements of the FHSA, 15 U.S.C. § 1262(c); and (4) ban certain hazardous substances altogether, 15 U.S.C. § 1261(q)(1). The CPSC regulates children toys, and it

has determined that the following types of toys or other articles intended for use by children present a mechanical hazard . . . because in normal use, or when subjected to reasonably foreseeable damage or abuse, the design or manufacture presents an unreasonable risk of personal injury or illness:

. . . .

- (9) Any toy or other article intended for use by children under 3 years of age which presents a choking, aspiration, or ingestion hazard because of small parts as determined by Part 1501 of this chapter and which is introduced into interstate commerce after January 1, 1980. . . .

16 C.F.R. § 1500.18(a)(9). Section 1500.18(a)(9) is commonly referred to as the small parts regulation. See, e.g., United States v. Toys “R” Us, Inc., 754 F. Supp. 1050, 1054 (D.N.J. 1991)(Barry, J.)(discussing whether various toys are banned under § 1500.18(a)(9), the small parts regulation). Section 1500.18(a)(9) has three elements: (i) the toy or other article is “intended for use by children under 3 years of age”; (ii) the toy “presents a choking, aspiration, or ingestion hazard because of small parts”; and (iii) the toy has been “introduced into interstate commerce after January 1, 1980.” 16 C.F.R. § 1500.18(a)(9). If all three elements are met, the toy is a mechanical hazard. See 16 C.F.R. § 1500.18(a)(9).

1. **If a Toy is listed in § 1501.2(a) Then It Is Intended Definitively for Use by Children Under Three Years of Age; for Toys not Listed, the CPSC Uses the**

Three-Factor § 1501.2(b) Test to Determine Whether a Toy or Other Article Is Intended for Use by Children Under Three Years of Age.

Section 1501.2(a) first explains that the “scope” of § 1500.18(a)(9)’s ban “applies to all toys and other articles intended for use by children under 3 years (36 months) of age.” 16 C.F.R.

§ 1501.2(a). Section 1501.2(a) then provides a non-exhaustive list of nineteen “[s]uch articles”:

squeeze toys; teethingers; crib exercisers; crib gyms; crib mobiles; other toys or articles intended to be affixed to a crib, stroller, playpen, or baby carriage; pull and push toys; pounding toys; blocks and stacking sets; bathtub, wading pool and sand toys; rocking, spring, and stick horses and other figures; chime and musical balls and carousels; jacks-in-the-box; stuffed, plush, and flocked animals and other figures; preschool toys, games and puzzles intended for use by children under 3; riding toys intended for use by children under 3; infant and juvenile furniture articles which are intended for use by children under 3 such as cribs, playpens, baby bouncers and walkers, strollers and carriages; dolls which are intended for use by children under 3 such as baby dolls, rag dolls, and bean bag dolls; toy cars, trucks, and other vehicles intended for use by children under 3. In addition, such articles include any other toys or articles which are intended, marketed or labeled to be entrusted to or used by children under 3 years of age.

16 C.F.R. § 1501.2(a). See 16 C.F.R. § 1501.1 (explaining that § 1501.2(a) “describes certain articles that are subject to § 1500.18(a)(9)”). The § 1501.2(a) non-exhaustive list is divided into two parts; the first part contains fourteen toys that are intended definitively for use by children under three years of age:

squeeze toys; teethingers; crib exercisers; crib gyms; crib mobiles; other toys or articles intended to be affixed to a crib, stroller, playpen, or baby carriage; pull and push toys; pounding toys; blocks and stacking sets; bathtub, wading pool and sand toys; rocking, spring, and stick horses and other figures; chime and musical balls and carousels; jacks-in-the-box; stuffed, plush, and flocked animals and other figures

16 C.F.R. § 1501.2(a). The second part of enumerated toys contains five toys with the qualifier “intended for use by children under 3”:

preschool toys, games and puzzles intended for use by children under 3; riding toys intended for use by children under 3; infant and juvenile furniture articles which are intended for use by children under 3 such as cribs, playpens, baby bouncers and walkers, strollers and carriages; dolls which are intended for use by children under 3 such as baby dolls, rag dolls, and bean bag dolls; toy cars, trucks, and other

vehicles intended for use by children under 3.

16 C.F.R. § 1501.2(a). For this second set of toys, an additional determination must be made whether the toy is intended for use by children under three years of age by looking at the three § 1501.2(b) factors. If a toy is enumerated in the § 1501.2(a) list, then the toy is “intended for use by children under 3 years (36 months) of age.” 16 C.F.R. § 1501.2(a).⁴⁵ If a toy does not match one of the listed examples, then the regulation explains that the small parts prohibition “include[s] any other toys or articles which are intended, marketed or labeled to be entrusted to or used by children under 3 years of age.” 16 C.F.R. § 1501.2(a). To make this determination, § 1501.2(b) provides three factors: (i) “the manufacturer’s stated intent (such as on a label) if it is a reasonable one;” (ii) “the advertising, promotion, and marketing of the article;” and (iii) “whether the article is commonly recognized as being intended for children under 3.” 16 C.F.R. § 1501.2(b). The United States Court of Appeals for the Second Circuit summarizes, and explains that § 1501.2(a) lists covered toys and the § 1501.2(b) fills the gap for toys that are not enumerated:

First, we note that the non-exclusive listing of “covered products” provides a reasonable degree of guidance in assessing many articles (e. g., certain products, although not specifically enumerated, can easily be determined to belong to the broad category of “crib” toys, toys which obviously are intended for children under three years of age). To the extent that it remains uncertain whether an “unlisted” article falls within the coverage of the Small Parts Regulation, we believe that application of the three non-determinative criteria will resolve the issue satisfactorily in most, if not in all, cases. . . . New products, which the manufacturer may feel are “borderline,” may be submitted to the CPSC during their design and development stage, so that any potential future problems may be avoided at minimal inconvenience and expense to the manufacturer. . . . [M]anufacturers, either by reference to the listing of “covered products,” by application of the three nondeterminative criteria, or by requesting a determination from the CPSC, will be able in all cases to know in advance how to avoid an unlawful course of action

Toy Mfrs. of Am., Inc. v. Consumer Prod. Safety Comm’n, 630 F.2d 70, 78-79 (2d Cir. 1980)(footnote omitted).

⁴⁵The Court addresses this interpretation thoroughly in its Analysis § I, infra.

A. **The § 1501.2(b) Test Considers All Parties Involved With the Creation, Marketing, Sale, Purchase, and Use of the Toy to Determine Whether a Toy Is Intended For Use By Children Younger Than Three Years Old.**

If a toy is not listed in § 1501.2(a) -- or if the toy is listed, but contains the “is intended for use by children under 3” -- the next step is to determine whether the toy is intended for use by children under three years of age. See 16 C.F.R. § 1501.2. Section 1501.2(b) provides three factors to make the determination whether a toy is intended for use by children under three years of age: (i) “the manufacturer’s stated intent (such as on a label) if it is a reasonable one”; (ii) “the advertising, promotion, and marketing of the article”; and (iii) “whether the article is commonly recognized as being intended for children under 3.” 16 C.F.R. § 1501.2. Because § 1501.2 uses the passive voice, it is not evident who’s intent governs. See 16 C.F.R. § 1501.2(a) (“[S]uch articles include any other toys or articles which are intended”); 16 C.F.R. § 1501.2(b) (“[I]n determining which toys and other articles are intended for use by children under 3 years (36 months) of age”); 16 C.F.R. § 1501.2(c) (“This regulation does not apply to toys or articles which are solely intended for use by children 3 years of age or older.”). See, e.g., Dean v. United States, 556 U.S. 568, 572 (2009)(“The passive voice focuses on an event that occurs without respect to a specific actor, and therefore without respect to any actor’s intent or culpability.”); Watson v. United States, 552 U.S. 74, 81 (2007)(noting that 18 U.S.C. § 924(d)(1)’s use of passive voice in the phrase “to be used” reflects “agnosticism . . . about who does the using”).

Two courts, in construing the FHSA and its regulations, have concluded that the regulations’ use of the word “intended” requires an objective test. See United States v. Focht, 882 F.2d 55, 58-59 (3d Cir. 1989); United States v. Articles of Banned Hazardous Substances Consisting of 1030 Gross (More or Less) of Baby Rattles, 614 F. Supp. 226, 231 (E.D.N.Y. 1985)(Glasser, J.). The Honorable I. Leo Glasser, United States District Judge for the United

States District Court for the Eastern District of New York, concludes that the “only rational interpretation of the word ‘intended’” in the FHSA “calls for an objective test of intent: whether a reasonable person would believe that the object is a toy or article intended for use by children.”

United States v. Articles of Banned Hazardous Substances Consisting of 1030 Gross (More or Less) of Baby Rattles, 614 F. Supp. at 231 (quoting 15 U.S.C. § 1261(f)(1)(D)). Judge Glasser explains:

[T]he language of the FHSA itself . . . nowhere speaks specifically of the manufacturer’s subjective intent. Instead, the FHSA merely defines a hazardous substance as “[a]ny toy or other article intended for use by children” which are found by the Commission to present electrical, mechanical or thermal dangers that make them hazardous to children. 15 U.S.C. § 1261(f)(1)(D). The only rational interpretation of the word “intended” in the statute calls for an objective test of intent: whether a reasonable person would believe that the object is a toy or article intended for use by children. Under such a test, the defendant rattles must be considered toys or articles intended for use by children. The subjective interpretation of intent urged by claimant could seriously diminish the effectiveness of FHSA because it would enable a manufacturer to introduce dangerous articles into commerce on the unreasonable but good faith belief that the articles would not be used by children. Such a result could not possibly comport with the intent of Congress in enacting the FHSA.

. . . .

Permitting a manufacturer to claim its “intent” is that the product will not be used as a toy, despite evidence of its use as a toy and a common sense observation that children would be likely to use it as a toy, would thwart the purpose of the FHSA and regulations.

United States v. Articles of Banned Hazardous Substances Consisting of 1030 Gross (More or Less) of Baby Rattles, 614 F. Supp. at 231-32 & n.9. The United States Court of Appeals for the Third Circuit analyzes regulations banning “kits and components intended to produce” hazardous fireworks and concludes that language of the “regulations clearly contemplate an objective seller standard.” United States v. Focht, 882 F.2d at 58 (concluding that the regulatory “language calls for application of an objective seller standard” and rejecting the “district court’s subjective

consumer standard,” which looks to how the consumer intended to use the components). See United States v. Articles of Banned Hazardous Substances Consisting of an Undetermined No. of Cans of Rainbow Foam Paint, 34 F.3d 91, 98 (2d Cir. 1994)(“We conclude that the language of § 1261(q)(1)” which defines a banned hazardous substance, “focuses on the intended user of the product, and, therefore, the fact that [the product] is purchased by adults is irrelevant.”); R. B. Jarts, Inc. v. Richardson, 438 F.2d 846, 853-54 (2d Cir. 1971)(“A manufacturer, knowing that lawn darts can be and have frequently been used by children, . . . [cannot] deny that darts which are not so labeled or which are sold in toy stores are a ‘toy or other article intended for use by children.’”)(quoting 15 U.S.C. § 1261(q)(1)).

Before the CPSC promulgated the small parts regulation, the United States Court of Appeals for the District of Columbia analyzed whether a bicycle was a “‘toy, or other article intended for use by children’” under the FHSA’s jurisdiction, where the CPSC “found [that] the distinction between adult and children’s bicycles” was “difficult to draw.” Forester v. Consumer Prod. Safety Comm’n of U.S., 559 F.2d 774, 784 (D.C. Cir. 1977)(quoting 15 U.S.C. § 1261(q)(1)(A)).⁴⁶ Several bicycle organizations and individuals challenged the CPSC’s regulation of all bicycles, arguing that under the FHSA, the CPSC had jurisdiction only to regulate bicycles intended for children, not bicycles intended for adults. See Forester v. Consumer Prod. Safety Comm’n of U.S., 559 F.2d at 782. The CPSC sought to regulate all bicycles, because

“bicycles can be, and are used by children and adolescents. It is clear there is no precise way of distinguishing between those bicycles intended exclusively for adults and those intended for children as well as adults. Neither the manufacturer nor the retailer can accurately predict who the subsequent user will be, nor can the seller predict whether the adult purchaser will be the exclusive user or whether the purchaser will give the bike to a child or share it with a child. Indeed, the bicycle may be purchased exclusively for adult use, and when a child in the family becomes

⁴⁶The FHSA’s definition of “banned hazardous substance” under 15 U.S.C. § 1261(q)(1)(A) remains the same today.

physically able to ride it the use may change. Moreover, an adult purchaser may subsequently sell the bicycle to a parent for a child's use."

Forester v. Consumer Prod. Safety Comm'n of U.S., 559 F.2d at 784-85 (quoting 39 Fed. Reg. 26100 (1974)). The D.C. Court of Appeals reasoned:

[T]he [CPSC's] power under the FHSA to regulate items for adult use should not be construed too expansively. . . . The language and intent of the FHSA turn upon intended use. As [the plaintiff] seems implicitly to recognize, the relevant intent is like that in tort law a result is intended if it is a reasonably foreseeable result of one's actions. Incidental use of an item by adults would not deprive the [CPSC] of jurisdiction to regulate the item under the FHSA, and incidental use by children would not create such jurisdiction.

Determination of such "intent," however, is vested in the sound discretion of the [CPSC]. This is particularly so "[b]etween the[] ends of the spectrum," where . . . full-sized bicycles fall. [R. B. Jarts, Inc. v. Richardson, 438 F.2d 846, 852 (2d Cir. 1971).] In view of the evidence considered by the [CPSC] in this case, we cannot conclude that it abused its discretion or acted contrary to law in determining that all bicycles except those excluded from the regulations are "intended for use by children."

Forester v. Consumer Prod. Safety Comm'n of U.S., 559 F.2d at 786 (citing W. Prosser, Torts 31-34 (4th ed. 1971)). For the proposition that the FHSA's use of "intent is like that in tort law," where "a result is intended if it is a reasonably foreseeable result of one's actions," the D.C. Court of Appeals explains:

The FHSA is drafted in terms that strongly suggest intent to rely on tort law foreseeability concepts. For example, "hazardous substance" is defined in part as one that "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use" 15 U.S.C. § 1261(f)(1)(A) (1970).^[47] The [CPSC] is empowered to determine that an article "present(s) a mechanical hazard if in normal use or when subjected or reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness" 15 U.S.C. § 1261(s) (1970).^[48]

⁴⁷This definition remains the same today. See 15 U.S.C. § 1261(f)(1)(A).

⁴⁸This definition remains largely the same today. See 15 U.S.C. § 1261(s) ("An article may be determined to present a mechanical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness")

This construction also finds support in the legislative history:

Common to each of the definitions (of electrical, mechanical and thermal hazards) is the phrase “in normal use or when subjected to reasonably foreseeable damage or abuse.” The phrase places a significant duty upon the manufacturer of any toy or article intended for use by children. Not only must he consider the safety of the product in normal use, he must also consider the safety of the article after damage or abuse after predicting what the child using the toy will reasonably do to it or with it.

Forester v. Consumer Prod. Safety Comm’n of U.S., 559 F.2d at 786 n.14 (quoting S. Rep. No. 91-237 S. Rep. No. 91-237, 91st Cong., 1st Sess. 6 (1969), and citing W. Prosser, Torts 31-34 (4th ed. 1971), and H.R. Rep. No. 91-389, 91st Cong., 1st Sess. 12-13 (1969)). Elsewhere, the FHSA and the regulations also focus on reasonable foreseeability: § 1500.3(c)(10) explains that the FHSA’s definition of a “misbranded hazardous substance”

is supplemented by the following definitions or interpretations of terms used therein:

- (i) Hazardous substances intended, or packaged in a form suitable, for use in the household means any hazardous substance, whether or not packaged, that under any customary or reasonably foreseeable condition of purchase, storage, or use may be brought into or around a house, apartment, or other place where people dwell, or in or around any related building or shed including, but not limited to, a garage, carport, barn, or storage shed. . . . [T]he test shall be whether under any reasonably foreseeable condition of purchase, storage, or use the article may be found in or around a dwelling.

16 C.F.R. § 1500.3(c)(10). See 15 U.S.C. §§ 1261(h)(1), 1261(r), 1261(s), 1261(t), 1277, 1278a.

Turning to other sections of the FHSA, ““there is a natural presumption that identical words used in different parts of the same act are intended to have the same meaning.”” Bd. of Cty. Commissioners of Boulder Cty. v. Suncor Energy (U.S.A.) Inc., 965 F.3d 792, 807 (10th Cir. 2020)(quoting Atl. Cleaners & Dyers v. United States, 286 U.S. 427, 433 (1932)). A key-word search reveals that the FHSA uses the word “intended” in six sections, and there are forty-six

corresponding regulations that use it. Although, there is no similar presumption that the word “intended” has the same meaning in related statutes, see Bd. of Cty. Commissioners of Boulder Cty. v. Suncor Energy (U.S.A.) Inc., 965 F.3d at 807 (“[N]o such presumption applies to the same word used in different statutes.”), the Consumer Product Safety Act’s, 15 U.S.C. §§ 2051-2089 (“CPSA”),⁴⁹ which established the CPSC, also relies on the same three § 1501.2(b) factors to determine whether a toy or product is a “children’s product,” 15 U.S.C. § 2052(a)(2), and the three factors are found elsewhere in the CPSA’s regulations, see 16 C.F.R. §§ 1200.2(c). See also 16 C.F.R. § 1500.19(c). The CPSA uses the word “intended” in eight sections and eighty-seven times in the CPSA’s corresponding regulations. Both the CPSA and its regulations -- 15 U.S.C. § 2052(a)(2) and 16 C.F.R. § 1200.2(c) -- however, use an additional fourth factor⁵⁰ to “determine whether a consumer product is primarily intended for a child 12 years of age or younger,” 15 U.S.C. § 2052(a)(2); 16 C.F.R. § 1200.2(c), unlike § 1501.2(b), which focuses on children age three or older. In addition, § 1200.2(c) provides detailed instructions for how to determine a toy’s intended age. See 16 C.F.R. § 1200.2(c). Although (i) § 1501.2(b) does not incorporate § 1200.2(c)’s extensive examples, (ii) focuses on children three years or older as opposed twelve years and older, and (iii) does not include as a fourth factor the Age Determination Guidelines, § 1200.2(c) is instructive, because § 1200.2(c) highlights that (i) the age determination focuses on the manufacturer’s actions, but also considers the entire distribution chain; (ii) that third-party

⁴⁹The CPSA established the CPSC, defines CPSC’s basic authority, authorizes the CPSC to develop standards and bans, and gives CPSC the authority to pursue recalls. See 15 U.S.C. §§ 2051-2089.

⁵⁰In addition to the three factors in 16 C.F.R. § 1501.2(b), both 15 U.S.C. § 2052(a)(2) and 16 C.F.R. § 1200.2 include a fourth factor: “The Age Determination Guidelines issued by the Consumer Product Safety Commission staff in September 2002, and any successor to such guidelines.” 15 U.S.C. § 2052(a)(2)(D); 16 C.F.R. § 1200.2(a)(1)(iv).

perceptions, such as consumers, are taken into consideration; and (iii) the manufacturer's subjective intent is not taken into consideration. See 16 C.F.R. § 1200.2(c). Under § 1200.2(c), “[t]o determine whether a consumer product is primarily intended for a child 12 years of age or younger the four specified statutory factors must be considered together as a whole. The following four factors must be considered”:

- (1) A statement by a manufacturer about the intended use of such product, including a label on such product if such statement is reasonable. A manufacturer's statement about the product's intended use, including the product's label, should be reasonably consistent with the expected use patterns for a product. A manufacturer's statement that the product is not intended for children does not preclude a product from being regulated as a children's product if the primary appeal of the product is to children 12 years of age or younger, as indicated, for example, by decorations or embellishments that invite use by the child, being sized for a child or being marketed to appeal primarily to children. Similarly, a label indicating that a product is for ages 9 and up does not necessarily make it a children's product if it is a general use product. Such a label may recommend 9 years old as the earliest age for a prospective user, but may or may not indicate the age for which the product is primarily intended. The manufacturer's label, in and of itself, is not considered to be determinative.
- (2) Whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger.
 - (i) These representations may be express or implied. For example, advertising by the manufacturer expressly declaring that the product is intended for children 12 years of age or younger will support a determination that a product is a children's product. While, for example advertising by the manufacturer showing children 12 years of age or younger using the product may support a determination that the product is a children's product. These representations may be found in packaging, text, illustrations and/or photographs depicting consumers using the product, instructions, assembly manuals, or advertising media used to market the product.
 - (ii) The product's physical location near, or visual association with, children's products may be a factor in making an age

determination, but is not determinative. For example, a product displayed in a children's toy section of a store may support a determination that the product is a children's product. However, where that same product is also sold in department stores and marketed for general use, further evaluation would be necessary. The [CPSC] recognizes that manufacturers do not necessarily control where a product will be placed in a retail establishment and such lack of control will be considered. The [CPSC] evaluates products more broadly than on a shelf-by-shelf or store-by-store basis.

- (iii) The product's association or marketing in conjunction with nonchildren's products may not be determinative as to whether the product is a children's product. For example, packaging and selling a stuffed animal with a candle would not preclude a determination that the stuffed animal is a children's product since stuffed animals are commonly recognized as being primarily intended for children.
- (3) Whether the product is commonly recognized by consumers as being intended for use by children 12 years of age or younger. Consumer perception of the product's use by children, including its reasonably foreseeable use, will be evaluated. Sales data, market analyses, focus group testing, and other marketing studies may help support an analysis regarding this factor.
 - (i) Features and Characteristics -- additional considerations that may help distinguish children's products from nonchildren's products include:
 - (A) Small sizes that would not be comfortable for the average adult;
 - (B) Exaggerated features (large buttons, bright indicators) that simplify the product's use;
 - (C) Safety features that are not found on similar products intended for adults;
 - (D) Colors commonly associated with childhood (pinks, blues, bright primary colors);
 - (E) Decorative motifs commonly associated with childhood (such as animals, insects, small vehicles, alphabets, dolls, clowns, and puppets);
 - (F) Features that do not enhance the product's utility (such as cartoons) but contribute to its attractiveness to children 12

years of age or younger; and

- (G) Play value, i.e., features primarily attractive to children 12 years of age or younger that promote interactive exploration and imagination for fanciful purposes (whimsical activities lacking utility for accomplishing mundane tasks; actions performed for entertainment and amusement).
 - (ii) Principal use of the product -- the principal uses of a product take precedence over other actions that are less likely to be performed with a product. For example, when a child pretends that a broom is a horse, that does not mean the item is a children's product because the broom's principal use is for sweeping;
 - (iii) Cost -- the cost of a given product may influence the determination of the age of intended users; and
 - (iv) Children's interactions, if any, with the product—products for use in a child's environment by the caregiver but not for use by the child would not be considered to be primarily intended for a child 12 years of age or younger.
- (4) The Age Determination Guidelines issued by the Consumer Product Safety Commission staff in September 2002, and any successor to such guidelines. The product's appeal to different age groups and the capabilities of those age groups may be considered when making determinations about the appropriate user groups for products.

16 C.F.R. § 1200.2(c)(1)-(4).

Section 1501.2's passive voice presents a challenge to the courts interpreting the phrase "toys . . . intended for use by children" 16 C.F.R. § 1501.2(b). See 16 C.F.R. § 1501.2(a) ("[T]oys or articles which are intended . . . to be . . . used by . . . children under 3 years of age."); 16 C.F.R. § 1501.2(b) ("[I]n determining which toys and other articles are intended for use by children under 3 years (36 months) of age"). Because of the regulation's passive voice, it is not evident who's intent governs. See, e.g., Dean v. United States, 556 U.S. at 572 ("The passive voice focuses on an event that occurs without respect to a specific actor, and therefore without respect to any actor's intent or culpability."); Watson v. United States, 552 U.S. at 81 (noting that 18 U.S.C. § 924(d)(1)'s use of passive voice in the phrase "to be used" reflects "agnosticism . . .

about who does the using”). The first option is that the manufacturer’s subjective intent governs.⁵¹ The second possibility looks at the actions and perceptions of the entire distribution chain. Third possible interpretation is that it broadly seeks the intent of the toy industry. Another interpretation is one that § 1501.2 includes some of the former plus some of the consumers. As much as the Court would prefer to construe § 1501.2 so that it is evident who performs the action -- i.e.: “To determine whether a manufacturer intended the toy and other article to be used by children under 3 years (36 months) of age, the following three factors are relevant: . . .” -- the Court should not and will not re-write or add words to the FHSA and the CPSC’s regulation. E.g., Dean v. United States, 556 U.S. at 572 (“[W]e ordinarily resist reading words or elements into a statute that do not appear on its face.”)(quoting Bates v. United States, 522 U.S. 23 (1997)); Exby-Stolley v. Bd. of Cty. Commissioners, 979 F.3d 784, 791 (10th Cir. 2020)(“[E]ffectively add[ing] language to

⁵¹The Second Circuit suggests that the focus is on the manufacturer:

[E]ven though no one of these criteria will be considered dispositive, the manufacturer obviously has complete control in labeling a product as being one intended for children in a particular age group, and is not powerless to influence the advertising and promotion of a product in a manner consistent with its age group labeling. Therefore, if a manufacturer reasonably labels an article as being intended for children over three years of age, and takes steps to insure that the article is so advertised and promoted, we cannot perceive how the general public could form an impression that the article actually is intended for children under three years of age as well. For all practical purposes, it appears to us that the manufacturers themselves are fairly capable of taking action to remove any doubts as to whether a particular article falls within the coverage of the Small Parts Regulation. . . . New products, which the manufacturer may feel are “borderline,” may be submitted to the CPSC during their design and development stage, so that any potential future problems may be avoided at minimal inconvenience and expense to the manufacturer.

Toy Mfrs. of Am., Inc. v. Consumer Prod. Safety Comm’n, 630 F.2d 70, 78 (2d Cir. 1980)(footnotes omitted). The Court disagrees that the manufacturer’s intent controls, because the regulations only discuss the manufacturer’s intent in the first factor, the second and third factors are broader, and the passive voice does not signal who’s intent controls.

the [statutes] plain text . . . ordinarily . . . is an impermissible method of interpreting the governing statutory law.”). Accordingly, because the three § 1501.2 factors do not specify the actor, the Court concludes that the regulation considers all parties involved with the creation, marketing, sale, purchase, and use of the toy to determine whether a toy is intended for use by children younger than three years old: namely, the entire distribution chain -- the manufacturer, the distributor, the retailer, and the consumer -- as well as the parties involved with the advertising, promotion, and marketing of the toy, and the relevant toy industry. See 16 C.F.R. § 1501.2(b). Cf. 16 C.F.R. § 1200.2(c)(3)(“Consumer perception of the product’s use by children, including its reasonably foreseeable use, will be evaluated. Sales data, market analyses, focus group testing, and other marketing studies may help support an analysis regarding [the third] factor.”). In other words, the Court steps back from the trees and looks at a distance at the entire forest, and asks what everyone involved with the toy -- taken collectively -- intends for the product. Realistically, the issue is what is the intent of all the people involved with the toy. The Court, in addition, concludes that the three § 1501.2(b) factors are all objective⁵² considerations: (i) the first factor considers the

⁵²Although, the Court concludes that the three § 1501.2(b) factors are objective, the Court will not read an “objective test of intent” -- “whether a reasonable person would believe that the object is a toy or article intended for use by children” -- into the regulation as Judge Glasser does into the FHSA, see United States v. Articles of Banned Hazardous Substances Consisting of 1030 Gross (More or Less) of Baby Rattles, 614 F. Supp. at 231, because (i) a reasonable person test is absent from § 1501.2’s language, the corresponding regulations, and the FHSA; (ii) such an objective test adds words to the forest that is invented or manufactured rather than the real person and entities involved with the product; and (iii) adds and a concept that is not in the statute or regulation, which violates the principle that Courts should not add or read in words that Congress has not in the statute. See Dean v. United States, 556 U.S. at 572; Exby-Stolley v. Bd. of Cty. Commissioners, 979 F.3d at 791.

The Court agrees, however, with the D.C. Court of Appeals and the Third Circuit that the FHSA’s use of “intent is like that in tort law,” where “a result is intended if it is a reasonably foreseeable result of one’s actions,” Forester v. Consumer Prod. Safety Comm’n of U.S., 559 F.2d at 786 (citing W. Prosser, Torts 31-34 (4th ed. 1971)); see United States v. Focht, 882 F.2d at 59, because the small parts regulation requires an examination whether a toy “intended for use by children” presents a mechanical hazard, because of “small parts” “when subjected to reasonably

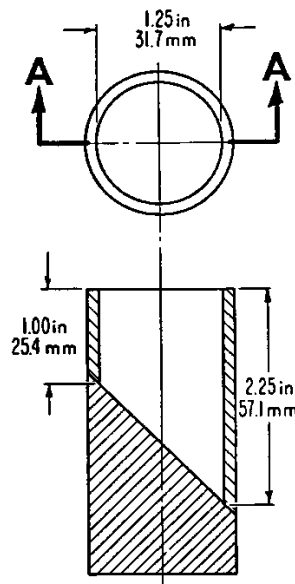
manufacturer's stated intent, if it is reasonable, not the manufacturer's subjective intent; (ii) the second factor considers the steps that everyone involved with the toy, taken collectively, took in advertising, promoting, and marketing the toy -- none of which are subjective considerations; and (iii) the third factor asks how the toy is commonly recognized, which only includes subjective perceptions in the aggregate, and where neither the manufacturer's or a single buyer's subjective perception or intent is relevant. See 16 C.F.R. § 1501.2(b). See also United States v. Articles of Banned Hazardous Substances Consisting of 1030 Gross (More or Less) of Baby Rattles, 614 F. Supp. at 232 n.9 ("Permitting a manufacturer to claim its 'intent' is that the product will not be used as a toy, despite evidence of its use as a toy and a common sense observation that children would be likely to use it as a toy, would thwart the purpose of the FHSA and regulations."); United States v. Focht, 882 F.2d at 61 (rejecting the "seller's subjective intent standard"); R. B. Jarts, Inc. v. Richardson, 438 F.2d at 853-54 ("A manufacturer, knowing that lawn darts can be and have frequently been used by children, . . . [cannot] deny that darts . . .[,] which are sold in toy stores[,] are a 'toy or other article intended for use by children.'")(quoting 15 U.S.C. § 1261(q)(1)); Forester v. Consumer Prod. Safety Comm'n of U.S., 559 F.2d at 786 (concluding that the FHSA's use of "intent is like that in tort law," where "a result is intended if it is a reasonably foreseeable result of

foreseeable damage or abuse," 16 C.F.R. § 1500.18(a)(9), as well as the FHSA's repeated use of "reasonably foreseeable," 15 U.S.C. §§ 1261(f)(1)(A), 1261(s), 1277(b), 1277(d), 1278a(b)(1)(A). See also 16 C.F.R. §§ 1500.12-1505.6. The FHSA regulations uses "reasonably foreseeable" in thirty-four sections. See, e.g., 16 C.F.R. § 1500.3(c)(10)(i); 16 C.F.R. § 1500.50(a) ("The objective of §§ 1500.51, 1500.52, and 1500.53 is to describe specific test methods for simulating normal use of toys and other articles intended for use by children as well as the reasonably foreseeable damage or abuse to which the articles may be subjected. The test methods are for use in exposing potential hazards that would result from the normal use or the reasonably foreseeable damage or abuse of such articles intended for children."); 16 C.F.R. § 1505.4(d)(1) ("A toy shall be designed and constructed to have the strength and rigidity necessary to withstand reasonably foreseeable damage and abuse without producing or increasing a shock, fire, or other accident hazard.").

one's actions"). Cf. 16 C.F.R. § 1200.2(c)(1) ("The manufacturer's label, in and of itself, is not considered to be determinative.").

2. The Test Method Used to Determine Whether a Toy Presents a Choking, Aspiration, or Ingestion Hazard.

The first step to determine whether a children's toy presents a choking, aspiration or ingestion hazard is to place the toy into a cylinder -- the small parts cylinder -- defined in Figure 1 of § 1501.4. See 16 C.F.R. § 1501.4(a) ("In testing to ensure compliance with this regulation, the dimensions of the Commission's test cylinder will be no greater than those shown in Figure 1."). The small parts cylinder has a diameter of one-and-one-quarter inches and a depth which slopes at a forty-five-degree angle from one inch to two-and-one-quarter inches:



Section A-A

FIG 1--SMALL PARTS CYLINDER

16 C.F.R. § 1501.4, Figure 1. If the toy fits, without compression, in any orientation, entirely within the small parts cylinder, the children's toy presents a choking, aspiration or ingestion hazard. See 16 C.F.R. § 1501.4(a), (b)(1). Any detached components are tested in the same manner. See 16 C.F.R. § 1501.4)(b)(1).

Second, “[i]f the article does not fit entirely within the cylinder, subject it to the appropriate ‘use and abuse’ tests of 16 CFR 1500.51 and 1500.52.” 16 C.F.R. § 1501.4(b)(2). “The ‘use and abuse’ battery of tests . . . simulate the normal and reasonably foreseeable use, damage or abuse of the toy or other article by a child in the age group for which that toy or article is intended.” United States v. Toys “R” Us, Inc., 754 F. Supp. at 1054. Section 1500.51 describes the use and abuse tests for toys “intended for use by children 18 months of age or less,” 16 CFR § 1500.51, and § 1500.51 describes the use and abuse for toys “intended for use by children over 18 but not over 36 months,” 16 CFR § 1500.52. Under the “use and abuse” tests, toys are subject to: (i) an impact test; (ii) a flex test; (iii) a torque test; (iv) a tension test; and (iv) a compression test. See 16 CFR §§ 1500.51(b)-(g), 1500.52(b)-(g). The tests differ in that toys intended for younger children are subject to a more rigorous testing requirements. Compare 16 CFR § 1500.51(b)(requiring that, for toys intended for children younger than eighteen months, toys be dropped ten times from a height of four-and-a-half feet), with 16 C.F.R. § 1500.52(b)(requiring that, for toys intended for children older than eighteen months but younger than thirty-six months, toys be dropped four times from a height of three feet). If “[a]ny components or pieces (excluding paper, fabric, yarn, fuzz, elastic, and string) . . . have become detached from the article” or toy “as a result of the use and abuse testing,” that detached component or piece is then placed into the small parts cylinder “one at a time. If any such components or pieces fit entirely within the cylinder, in any orientation and without being compressed, the article fails to comply with the test procedure,” and is considered a choking, aspiration or ingestion hazard. 16 CFR § 1501.4(b)(2).

3. The Definition of Whether a Toy has Been Introduced into Interstate Commerce.

Section 1500.18(a)(9) provides:

For purposes of this regulation, introduction into interstate commerce is defined as follows: A toy or children’s article manufactured outside the United States is

introduced into interstate commerce when it is first brought within a U.S. port of entry. A toy or children's article manufactured in the United States is introduced into interstate commerce (1) at the time of its first interstate sale, or (2) at the time of its first intrastate sale if one or more of its components and/or raw materials were received interstate, whichever occurs earlier. Part 1501 defines the term "toy or other article intended for use by children under 3," as used in this regulation, and exempts certain products from banning under this regulation.

16 C.F.R. § 1500.18(a)(9).

4. Exemptions from the Small Parts Regulation.

If a toy is "solely intended for use by children 3 years of age or older," § 1500.18(a)(9) does not apply. 16 C.F.R. § 1501.2(c). Section 1500.18(a)(9) also "does not apply to all articles to which children under 3 years of age might have access simply because of presence in a household." 16 C.F.R. § 1501.2(c). In addition, several items are explicitly exempted from § 1500.18(a)(9):

- (a) Balloons;
- (b) Books and other articles made of paper;
- (c) Writing materials such as crayons, chalk, pencils, and pens;
- (d) Children's clothing and accessories, such as shoe lace holders and buttons;
- (e) Grooming, feeding, and hygiene products, such as diaper pins and clips, barrettes, toothbrushes, drinking glasses, dishes and eating utensils;
- (f) Phonograph records;
- (g) Modeling clay and similar products;
- (h) Fingerpaints, watercolors, and other paint sets;
- (i) Rattles (as defined at 16 CFR 1510.2); and
- (j) Pacifiers (as defined at 16 CFR 1511.2(a)).

16 C.F.R. § 1501.3.

5. Labeling Toys with Small Parts that Present a Choking Hazard.

Hazardous substances that do not bear a label in accordance with the requirements of 15 U.S.C. § 1261(p)(1) are a “misbranded hazardous substance,” and the introduction of such items into interstate commerce is prohibited. See 15 U.S.C. § 1262(b). A hazardous substance, including toys, is misbranded if the item is “intended, or packaged in a form suitable, for use in the household or by children,” where packaging or labeling “fails to bear a label”:

(1) which states conspicuously (A) the name and place of business of the manufacturer, packer, distributor or seller; . . . (D) the signal word “WARNING” or “CAUTION” on all other hazardous substances; (E) an affirmative statement of the principal hazard or hazards, such as “Flammable”, “Combustible”, “Vapor Harmful”, “Causes Burns”, “Absorbed Through Skin”, or similar wording descriptive of the hazard; . . . and (J) the statement (i) “Keep out of the reach of children” or its practical equivalent, or, (ii) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard

15 U.S.C. § 1261(p). The regulations further explain that a toy is misbranded if its

packaging, any descriptive material^[53] that accompanies them, and, if unpackaged and unlabeled, any bin in which they are held for sale, any container in which they are held for retail display, or any vending machine from which they are dispensed, fails to bear the labeling statements required . . . [by] this section, or if such labeling statements fail to comply with the prominence and conspicuousness requirements of paragraph (d) of this section before.

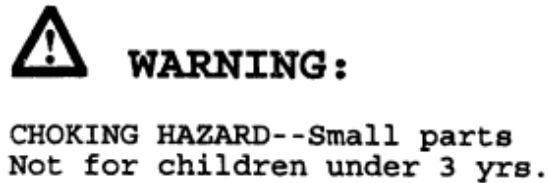
16 C.F.R. § 1500.19(b). If a toy is “intended for children who are at least three years old but less than six years of age” and “if the toy or game includes a small part,” the toy must “bear or contain

⁵³The regulations define “descriptive material” as

any discrete piece of written material separate from the label of the package that contains an instruction (whether written or otherwise) for the use of a product subject to these labeling requirements, any depiction of the product, and any written material that specifically describes any function, use, warnings, user population, design or material specification, or other characteristic of the product.

16 C.F.R. § 1500.19(a)(7).

the following cautionary statement”:



16 C.F.R. § 1500.19(b)(1).⁵⁴

LAW REGARDING STATUTORY CONSTRUCTION

When interpreting statutes, the Court must start with the plain language. See, e.g., Been v. O.K. Industries, Inc., 495 F.3d 1217, 1227 (10th Cir. 2007)(“We review issues of statutory construction de novo, interpret[ing] the words of the statute in light of the purposes Congress sought to serve.”)(internal quotations and citations omitted). “It is well established that when the statute’s language is plain, the sole function of the courts -- at least where the disposition required by the text is not absurd -- is to enforce it according to its terms.” Lamie v. U.S. Trustee, 540 U.S. 526, 534 (2004)(internal quotations omitted). See In re Trans Alaska Pipeline Rate Cases, 436 U.S. 631, 643 (1978)(noting that a court may not disregard the statute’s plain language unless a literal application of the statutory language “would lead to absurd results . . . or would thwart the obvious purpose of the statute”)(internal quotations omitted). “Courts indulge a strong presumption that Congress expresses its intent through the language it chooses. Therefore, when

⁵⁴Section 1500.19 contains nearly verbatim the same test as § 1501.2(b) for determining the age for which the toy is intended:

Age of intended user. In determining the ages of the children for which any toy or article subject to this section is intended, the following factors are relevant: the manufacturer’s stated intent (such as the age stated on a label) if it is reasonable; the advertising, marketing, and promotion of the article; and whether the article is commonly recognized as being intended for children in this age group.

16 C.F.R. § 1500.19(c).

the terms of a statute are clear and unambiguous, our inquiry ends and we should stick to our duty of enforcing the terms of the statute as Congress has drafted it.” United Kingdom Ministry of Defence v. Trimble Navigation Ltd., 422 F.3d 165, 171 (4th Cir. 2005)(internal quotations omitted). See Public Lands Council v. Babbitt, 167 F.3d 1287, 1314 (10th Cir. 1999)(Seymour, C.J.)(“In examining . . . [statutory] language, we assume that the words chosen by Congress are employed in their ordinary sense and accurately express Congress’ [] legislative purpose.”).

LAW REGARDING REVIEWING AGENCY LEGAL INTERPRETATIONS

In promulgating and enforcing regulations, agencies must interpret federal statutes, their own regulations, and the Constitution of the United States of America, and Courts reviewing those interpretations apply three different deference standards, depending on the kind of law at issue. First, the federal judiciary accords considerable deference to an agency’s interpretation of a statute that Congress has tasked it with enforcing. See United States v. Undetermined Quantities of Bottles of an Article of Veterinary Drug, 22 F.3d 235, 238 (10th Cir. 1994). This is known as Chevron deference, named after the seminal case, Chevron, U.S.A., Inc. v. Natural Resource Defense Council, Inc., 467 U.S. 837 (1984)(“Chevron”).⁵⁵ Chevron deference is a two-step process⁵⁶ that first asks whether the statutory provision in question is clear and, if it is not, then

⁵⁵The case itself is unremarkable, uninformative, does not explicitly outline the now-familiar two-step process of applying Chevron deference, and does not appear to have been intended to become a “big name” case at all. Its author, the Honorable John Paul Stevens, former Associate Justice of the Supreme Court, insists that the case was never intended to create a regime of deference, and, in fact, Justice Stevens became one of Chevron deference’s greatest detractors in subsequent years. See generally Charles Evans Hughes, Justice Stevens and the Chevron Puzzle, 106 Nw. U. L. Rev. 551 (2012).

⁵⁶There is, additionally, a threshold step -- the so-called step zero -- which asks whether Chevron deference applies to the agency decision at all. See Cass R. Sunstein, Chevron Step Zero, 92 Va. L. Rev. 187 (2006). Step zero asks: (i) whether the agency is Chevron-qualified, meaning whether the agency involved is the agency charged with administering the statute -- for example, the EPA administers a number of statutes, among them the Clean Air Act, Pub. L. No. 88-206, 77

asks whether the agency's interpretation of the unclear statute is reasonable. See Maralex Resources, Inc. v. Barnhardt, 913 F.3d 1189 1198-99 (10th Cir. 2019). As the Tenth Circuit has explained,

we must be guided by the directives regarding judicial review of administrative agency interpretations of their organic statutes laid down by the Supreme Court in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 . . . (1984). Those directives require that we first determine whether Congress has directly spoken to the precise question at issue. If the congressional intent is clear, we must give effect to that intent. If the statute is silent or ambiguous on that specific issue, we must determine whether the agency's answer is based on a permissible construction of the statute.

United States v. Undetermined Quantities of Bottles of an Article of Veterinary Drug, 22 F.3d at 238 (citation omitted).

A number of policy considerations animate Chevron deference, among them: (i) statutory interpretation, i.e., that Congress, by passing extremely open-ended and vague organic statutes, grants discretionary power to the agencies to fill in the statutory gaps; (ii) institutional competency, i.e., that agencies are more competent than the courts at filling out the substantive law in their field; (iii) political accountability, i.e., that agencies, as executive bodies ultimately headed by the President of the United States of America, can be held politically accountable for their interpretations; and (iv) efficiency, i.e., that numerous, subject-matter specialized agencies can more efficiently promulgate the massive amount of interpretation required to maintain the modern

Stat. 392; (ii) whether the decision fits within the category of interpretations afforded the deference -- interpretation of contracts, the Constitution, and the agency's own regulations are not afforded Chevron deference, see, e.g., U.S. West, Inc. v. FCC, 182 F.3d 1224 (10th Cir. 1999)("[A]n unconstitutional interpretation is not entitled to *Chevron* deference."); and (iii) whether Congress intended the agency to "speak with the force of law" in making the decision in question, United States v. Mead Corp., 533 U.S. 218, 229 (2001) -- opinion letters by the agency, for example, do not speak with the force of law and are thus not entitled to Chevron deference, see Christensen v. Harris Cty., 529 U.S. 576 (2000). An affirmative answer to all three inquiries results in the agency's decision passing step zero.

regulatory state -- found in the Code of Federal Regulations and other places -- than a unified but Circuit-fragmented federal judiciary can.

When agencies interpret their own regulations -- to, for example, adjudicate whether a regulated party followed them -- courts accord agencies what is known as Auer or Seminole Rock deference. See Auer v. Robbins, 519 U.S. 452 (1997)(“Auer”); Bowles v. Seminole Rock & Sand Co., 325 U.S. 410 (1945). This deference is applied in the same manner as Chevron deference and is substantively identical. The Court has previously expressed its concerns about Auer deference. See, e.g., Mohon v. Agentra, 400 F. Supp. 3d 1189, 1221-25 (D.N.M. 2019); Jarita Mesa Livestock Grazing Ass’n v. U.S. Forest Service, 305 F.R.D. at 286-89. The Supreme Court recently addressed whether it should overrule Auer deference in Kisor v. Wilkie, 139 S. Ct. 2400, 2408 (2019). Although the Supreme Court declined to overrule Auer, the majority opinion took pains to “reinforce its limits.” 139 S. Ct. 2408. The Court noted that Auer deference is appropriate “only if a regulation is genuinely ambiguous,” “even after a court has resorted to all the standard tools of interpretation.” 139 S. Ct. 2414. To earn deference in this scenario, the agency’s interpretation must still be “reasonable.” 139 S. Ct. at 2415 (quoting Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 515 (1994)). Auer deference is also “unwarranted” “when a court concludes that an interpretation does not reflect an agency’s authoritative, expertise-based ‘fair, [or] considered judgment.’” 139 S. Ct. at 2414 (quoting Christopher v. SmithKline Beecham Corp., 567 U.S. 142, 155 (2012)). Deference is therefore not appropriate where the regulatory interpretation is not “the agency’s ‘authoritative’ or ‘official position,’ rather than any more ad hoc statement not reflecting the agency’s views,” 139 S. Ct. at 2416 (quoting United States v. Mead Corp., 533 U.S. 218, 257-59 (2001)(Scalia, J., dissenting)), does not “in some way implicate [the agency’s] substantive expertise,” 139 S. Ct. at 2417, or is a convenient, post hoc rationalization to

defend past agency action, see 139 S. Ct. at 2417.

Where a court determines that an agency decision lacks the force of law -- and hence Chevron does not apply -- courts must consider the decision “under the framework set forth in Skidmore.” Carpio v. Holder, 592 F.3d 1091, 1098 (10th Cir. 2010)(citing Skidmore v. Swift & Co., 323 U.S. 134 (1944)(“Skidmore”), and McGraw v. Barnhart, 450 F.3d 493, 500 (10th Cir. 2006)). Under this framework, which courts frequently label Skidmore deference, the “paramount consideration” is whether an agency’s “decision has ‘the power to persuade.’” Carpio v. Holder, 592 F.3d at 1098 (quoting Skidmore, 323 U.S. at 140). “Under Skidmore, the degree of deference given informal agency interpretations will ‘vary with circumstances, and courts have looked to the degree of the agency’s care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency’s position.’” S. Utah Wilderness All. v. Bureau of Land Mgmt., 425 F.3d 735, 759 (10th Cir. 2005)(quoting United States v. Mead Corp., 533 U.S. 218, 228 2 (2001)), as amended on denial of reh’g (Jan. 6, 2006). As the Honorable Antonin Scalia, then-Associate Justice for the Supreme Court, has explained: “Skidmore deference is a ‘statement of the obvious: A judge should take into account the well-considered views of expert observers.’” Hydro Res., Inc. v. U.S. E.P.A., 608 F.3d 1131, 1146 n.10 (10th Cir. 2010)(quoting United States v. Mead Corp., 533 U.S. at 250 (Scalia, J., dissenting)). Although the Supreme Court decided Skidmore four decades before it decided Chevron, Chevron did not “‘eliminate Skidmore’s holding that an agency’s interpretation may merit some deference whatever its form, given the specialized experience and broader investigations and information available to the agency and given the value of uniformity in its administrative and judicial understandings of what a national law requires.’” McGraw v. Barnhart, 450 F.3d at 501 (quoting United States v. Mead Corp., 533 U.S. at 234). Accordingly, under Skidmore, the “degree of deference . . . ‘var[ies] with circumstances, and

courts have looked to the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position.” Carpio v. Holder, 592 F.3d at 1098 (quoting United States v. Mead Corp., 533 U.S. at 228)(alteration added).

Last, courts afford agencies no deference in interpreting the Constitution. See U.S. West, Inc. v. FCC, 182 F.3d 1224, 1231 (10th Cir. 1999)(“[A]n unconstitutional interpretation is not entitled to *Chevron* deference. . . . [D]eference to an agency interpretation is inappropriate not only when it is conclusively unconstitutional, but also when it raises serious constitutional questions.” (citing, e.g., Rust v. Sullivan, 500 U.S. 173, 190-91 (1991))). Courts have superior competence in interpreting -- and constitutionally vested authority and responsibility to interpret -- the Constitution's content. The presence of a constitutional claim does not take a court's review outside of the APA, however -- § 706(2)(B) specifically contemplates adjudication of constitutional issues -- and courts must still respect agency fact-finding and the administrative record when reviewing agency action for constitutional infirmities; they just should not defer to the agency on issues of substantive legal interpretation. See, e.g., Robbins v. U.S. Bureau of Land Mgmt., 438 F.3d 1074, 1085 (10th Cir. 2006)(“We review Robbins' [constitutional] due process claim against the [agency] under the framework set forth in the APA.”).

ANALYSIS

The Court first addresses how to determine whether a toy is intended for use by children under three years of age. The Court concludes that 16 C.F.R. § 1501.2 is ambiguous as to how to determine whether a toy is intended for use by children under three years of age, because the regulation's plain language reasonably can be interpreted in two ways: either the § 1501.2(a) list is dispositive, or the § 1501.2(b) three-factor test controls. Because the regulation is ambiguous, the Court considers the legislative history, and concludes that, if a toy corresponds to one of the

examples listed in § 1501.2(a), it is intended definitively for use by children under three years of age. Because § 1501.2(a) lists flocked toys and it is undisputed that the Calico Critters Yellow Labrador Twins toy is a flocked toy with small parts that present a choking hazard, the Court concludes that the Calico Critters Yellow Labrador Twins toy violates 16 C.F.R. § 1500.18(a)(9) as a matter of law. Even if the Court were to consider the three-factor § 1501.2(b) test, questions of material fact exist regarding § 1501.2(b)'s three factors, including whether the manufacturer's stated intent, including the 3+ label, is reasonable; whether the Calico Critters Yellow Labrador Twins toy was marketed to children under three; and how the toy is commonly recognized; summary judgment would therefore be inappropriate. Turning to the Motion to Limit, the Court concludes that the experts may not testify on their interpretations of federal regulations and statutes, because such expert testimony invades the Court's role, and the experts may not testify to the three § 1501.2(b) factors, because the Court concludes that the Calico Critters Yellow Labrador Twins toy was intended for use by children under three years of age as a matter of law. The experts may testify to facts regarding the Complaint's other counts, including negligence. The Court attaches the four expert reports with redactions to its Memorandum Opinion and Order as Exhibits A through D, and the experts may not testify on the redacted portions.

I. BECAUSE § 1501.2(a) LISTS FLOCKED TOYS, FLOCKED TOYS ARE INTENDED DEFINITELY FOR USE BY CHILDREN UNDER THREE YEARS OF AGE.

The Plaintiffs allege that Epoch Everlasting is negligent per se, because the Calico Critters Yellow Labrador Twins toy violates 16 C.F.R. § 1500.18(a)(9), which bans children's toys intended for use by children under three years old that present a choking hazard. See Complaint ¶¶ 48-52, at 15-16. Epoch Everlasting argues it is not negligent per se, because, as a matter of law, the Yellow Labrador Twins toy is intended solely for children ages three and up, and § 1500.18(a)(9), therefore, does not apply. See MSJ at 5. Although § 1501.2(a) lists flocked toys

as covered by § 1500.18(a)(9), Epoch Everlasting argues that the “regulations at issue are self-explanatory and do not automatically ban flocked toys like the Yellow Labrador Twins.” MSJ at 5.

Four elements comprise a negligence per se cause of action in New Mexico. See Heath v. La Mariana Apartments, 2008-NMSC-017, ¶ 7, 143 N.M. 657, 180 P.3d 664, 666.

“(1) [T]here must be a statute which prescribes certain actions or defines a standard of conduct, either explicitly or implicitly, (2) the defendant must violate the statute, (3) the plaintiff must be in the class of persons sought to be protected by the statute, and (4) the harm or injury to the plaintiff must generally be of the type the legislature through the statute sought to prevent.”

Heath v. La Mariana Apartments, 2008-NMSC-0017, ¶ 7, 180 P.3d at 666 (quoting Archibeque v. Homrich, 1975-NMSC-066, ¶ 15, 88 N.M. at 532, 543 P.2d at 825). Negligence per se exists only where a statutory or regulatory provision imposes an absolute duty to comply with a specific requirement. See Heath v. La Mariana Apartments, 2008-NMSC-017, ¶¶ 8-9, 143 N.M. at 659, 180 P.3d at 666. It is a court’s task “to determine whether the statutory or regulatory provisions at issue define with specificity what is ‘reasonable’ in a particular circumstance, such that the [fact-finder] does not have to undertake that inquiry.” Heath v. La Mariana Apartments, 2008-NMSC-017, ¶ 9, 143 N.M. at 659, 180 P.3d at 666 (quoting Abeita v. Northern Rio Arriba Electric Cooperative, 1997-NMCA-097, ¶¶23-25 124 N.M. 97, 946 P.2d 1108,).

The relevant legal standard is provided in the small parts regulations. See 16 C.F.R. § 1500.18(a)(9). The CPSC has banned toys for use by children under three which pose a risk of choking on, aspirating on, or ingesting small parts:

[The CPSC] has determined that the following types of toys or other articles intended for use by children present a mechanical hazard . . . because in normal use, or when subjected to reasonably foreseeable damage or abuse, the design or manufacture presents an unreasonable risk of personal injury or illness:

. . . .

- (9) Any toy or other article intended for use by children under 3 years of age which presents a choking, aspiration, or ingestion hazard because of small parts as determined by Part 1501 of this chapter and which is introduced into interstate commerce after January 1, 1980. . . .

16 C.F.R. § 1500.18(a)(9).

Epoch Everlasting does not dispute that 16 C.F.R. § 1500.18(a)(9) “prescribes certain actions or defines a standard of conduct, either explicitly or implicitly,” or that D. Dedios’ death by choking on the Calico Critters Yellow Labrador Twins’ pacifier accessory is “the harm or injury” that “the legislature through the statute sought to prevent.” Heath v. La Mariana Apartments, 2008-NMSC-0017, ¶ 7, 143 N.M. at 659, 180 P.3d at 666 (quoting Archibeque v. Homrich, 1975-NMSC-066, ¶ 15, 88 N.M. at 532, 543 P.2d at 825). See MSJ at 1-8. The Court concludes, therefore, that elements one and four of negligence per se are satisfied. See Heath v. La Mariana Apartments, 2008-NMSC-0017, ¶ 7, 180 P.3d at 666. Epoch Everlasting focuses on elements two and three of negligence per se: Epoch Everlasting essentially argues that it did not “violate the statute,” and that D. Dedios is not “in the class of persons sought to be protected by the statute,” Heath v. La Mariana Apartments, 2008-NMSC-0017, ¶ 7, 180 P.3d at 666 (quoting Archibeque v. Homrich, 1975-NMSC-066, ¶ 15, 543 P.2d 820, 825), because the Calico Critters Yellow Labrador Twins toy is intended solely for use by children older than three years old, and D. Dedios was not yet three years old, see MSJ at 5-10.

Section 1500.18(a)(9) calls for a three-part inquiry: (i) whether a toy or other article is “intended for use by children under 3 years of age”; (ii) whether a toy “presents a choking, aspiration, or ingestion hazard because of small parts”; and (iii) whether the toy has “introduced into interstate commerce after January 1, 1980.” 16 C.F.R. § 1500.18(a)(9). Epoch Everlasting does not dispute that the Calico Critters Yellow Labrador Twins pose a choking, aspiration, or ingestion hazard, or that the toy was introduced into interstate commerce after January 1, 1980.

See MSJ at 1-8. The Court concludes that it is undisputed that the Calico Critters Yellow Labrador Twins’ accessories -- the pacifier and bottle accessory -- are small parts that present a choking hazard that were introduced into interstate commerce after January 1, 1980. See Factual Background § 2, supra (deeming it undisputed that the Calico Critters Yellow Labrador Twin toy fits within the small parts cylinder); MSJ Response § II(B) ¶¶ 11-12, at 9 (asserting this fact); Pollack-Nelson Depo. at 69:1-7; id. at 76:4-7.

The focus of the parties’ dispute is the small parts regulation’s first element: whether the Calico Critters Yellow Labrador Twins toy is intended for use by children under three years. See MSJ at 5-10; MSJ Response at 19-22. Section 1501.2 explains the scope of § 1500.18(a)(9): (i) it lists nineteen toys that § 1500.18(a)(9) applies to, including flocked toys, see 16 C.F.R. § 1501.2(a); (ii) sets out three factors to consider to determine whether a toy is intended for use by children under three years of age, see 16 C.F.R. § 1501.2(b); and (iii) states that § 1500.18(a)(9) does not apply to toys intended solely for use by children older than three years of age, see 16 C.F.R. § 1501.2(c). Epoch Everlasting argues that, before it “distributed the Yellow Labrador Twins, the product was tested and certified as appropriate for children ages 3 and up,” and that the small parts regulation “does not apply,” because the Calico Critters Yellow Labrador Twins toy labeled 3+ and “was intended for use by children over 3 years of age. . . . That the product is flocked is irrelevant because Part 1501 does not apply to products intended for children ages 3 and up. ” MSJ at 7-8. In contrast, the Plaintiffs contend that the Calico Critters Yellow Labrador Twins toy is “automatically subject to the small parts regulation as a matter of law” because it is flocked. MSJ Response at 19. The Court concludes that § 1501.2 is ambiguous as to how to determine whether a toy is intended for use by children under three years of age, because the regulation’s plain language can reasonably be read to refer to either the three-factor § 1501.2(b)

test, or the non-exhaustive § 1501.2(a) list. See United States v. Quarrell, 310 F.3d 664, 669 (10th Cir. 2002)(“A statute is ambiguous when it is ‘capable of being understood by reasonably well-informed persons in two or more different senses.’”)(quoting In re Geneva Steel Co., 281 F.3d 1173, 1178 (10th Cir. 2002)). Because the regulation’s plain language is ambiguous, the Court turns to the statutory history, which provides that any toy in the non-exhaustive § 1501.2(a) list is definitively for use by children under three years of age. See In re Geneva Steel Co., 281 F.3d at 1178. Because it is undisputed that the Calico Critters Yellow Labrador Twins toy is flocked, the Court concludes that the toy is intended for use by children under three years of age. See 16 C.F.R. § 1501.2(a). Accordingly, the Court concludes that the Calico Critters Yellow Labrador Twins toy violates § 1500.18(a)(9), because (i) the toy is intended for use by children under three years of age as a matter of law; (ii) it has small parts that present a choking hazard; and (iii) it was introduced into the stream of commerce after January 1, 1980. Further, even if the Court were to consider the three § 1501.2(b) factors, judgment as a matter of law is inappropriate, because there are factual disputes as to each factor.

A. SECTION 1501.2 IS AMBIGUOUS BECAUSE ITS PLAIN LANGUAGE CAN BE READ REASONABLY IN TWO WAYS.

Because the parties dispute whether the Calico Critters Yellow Labrador Twins toy was intended for use by children under three years of age, the Court’s first task is to pinpoint what standard is used to make that determination. Section 1501.2(a) explains that the scope of § 1500.18(a)(9) “applies to all toys and other articles intended for use by children under 3 years (36 months) of age,” and provides that

[s]uch articles include, but are not to limited to: squeeze toys; teethingers; crib exercisers; crib gyms; crib mobiles; other toys or articles intended to be affixed to a crib, stroller, playpen, or baby carriage; pull and push toys; pounding toys; blocks and stacking sets; bathtub, wading pool and sand toys; rocking, spring, and stick horses and other figures; chime and musical balls and carousels; jacks-in-the-box; stuffed, plush, and flocked animals and other figures; preschool toys, games and

puzzles intended for use by children under 3; riding toys intended for use by children under 3; infant and juvenile furniture articles which are intended for use by children under 3 such as cribs, playpens, baby bouncers and walkers, strollers and carriages; dolls which are intended for use by children under 3 such as baby dolls, rag dolls, and bean bag dolls; toy cars, trucks, and other vehicles intended for use by children under 3. In addition, such articles include any other toys or articles which are intended, marketed or labeled to be entrusted to or used by children under 3 years of age.

16 C.F.R. § 1501.2(a).⁵⁷ See 16 C.F.R. § 1501.1 (explaining that § 1501.2(a) “describes certain articles that are subject to § 1500.18(a)(9)”). Section 1501.2 also provides:

(b) In determining which toys and other articles are intended for use by children

⁵⁷The CPSA and the regulations incorporate the American Society for Testing and Materials (“ASTM”) F963-17 safety standards. See 15 U.S.C. § 2056b (a) (“ASTM F963 . . . shall be considered to be consumer product safety standards issued by the Commission”); 16 C.F.R. § 1250.2(a) (“Except as provided for in paragraphs (b) and (c) of this section, toys must comply with the provisions of ASTM F963-17.”). To the extent that there is any discrepancy between the regulations and the ASTM,

any provision of ASTM F963 that restates or incorporates an existing mandatory standard or ban promulgated by the Commission or by statute or any provision that restates or incorporates a regulation promulgated by the Food and Drug Administration or any statute administered by the Food and Drug Administration are not part of the mandatory standard incorporated in paragraph (a) of this section.

16 C.F.R. § 1250.2(b). See 15 U.S.C. § 2056b(a) (ASTM F963 does not apply where “any provision . . . restates or incorporates an existing mandatory standard or ban promulgated by the Commission or by statute or any provision that restates or incorporates a regulation promulgated by the Food and Drug Administration or any statute administered by the Food and Drug Administration.”). ASTM F963-17 provides a list for which the small parts regulation pertains to:

Squeeze toys, teethingers, crib exercisers, crib gyms, crib mobiles, toys intended to be affixed to a crib, stroller, playpen, or baby carriage, pull and push toys, pounding toys, blocks and stacking sets, bathtub, wading pool and sand toys, rocking, spring, and stick horses and other figures, chime and musical balls and carousels, jack-in-the-boxes, stuffed, plush, and flocked animals and other figures, and those preschool toys, games and puzzles, riding toys, dolls and animal figures, cars, trucks, and other vehicles that are intended for use by children under the age of three years.

ASTM F963-17 § A1.4.3.1. The Court concludes that ASTM F963-17 § A1.4.3.1 restates 16 C.F.R. § 1501.2(a), because it employs nearly identical language to § 1501.2(a) and also purports to explain the scope of the small parts regulation; therefore, § 1501.2(a) controls. See 16 C.F.R. § 1250.2(b).

under 3 years (36 months) of age, for purposes of this regulation, the following factors are relevant: the manufacturer's stated intent (such as on a label) if it is a reasonable one; the advertising, promotion, and marketing of the article; and whether the article is commonly recognized as being intended for children under 3.

- (c) This regulation does not apply to toys or articles which are solely intended for use by children 3 years of age or older. In addition, it does not apply to all articles to which children under 3 years of age might have access simply because of presence in a household. Certain articles which are specifically exempted from this regulation are listed in § 1501.3 below.

16 C.F.R. § 1501.2(b)-(c). It is undisputed that the Calico Critters Yellow Labrador Twins toy is flocked; the Plaintiffs contend therefore that the toy is “automatically subject to the small parts regulations as a matter of law,” because § 1501.2(a) lists flocked toys. MSJ Response at 19. The Court concludes that § 1501.2 is ambiguous, because the regulation's plain language is subject to two reasonable interpretations: (i) the three-factor § 1501.2(b) test explains how to determine whether a toy is for use by children under three years of age, and if a toy is described in § 1501.2(a), that is only a factor to consider under the three-factor subsection (b) test; or (ii) as the Plaintiffs argue, § 1501.2(a) explains how to determine whether a toy is for use by children under three years of age: if a toy is described in § 1501.2(a), it is for use by children under three years of age, and if it is not listed, then turn to the three-factor § 1501.2(b) test.

“The goal of statutory interpretation is to ‘ascertain the congressional intent and give effect to the legislative will.’” In re Taylor, 899 F.3d 1126, 1129 (10th Cir. 2018)(quoting Ribas v. Mukasey, 545 F.3d 922, 929 (10th Cir. 2008)). “In conducting this analysis,” a court “first turn[s] to the statute's plain language,” In re Taylor, 899 F.3d at 1129, as “[a] statute clear and unambiguous on its face must be interpreted according to its plain meaning,” In re Geneva Steel Co., 281 F.3d 1173, 1178 (10th Cir. 2002). See Schindler Elevator Corp. v. Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2364 (2019)(“In statutory interpretation disputes, a court's proper starting point lies in a careful examination of the ordinary meaning and structure of the law

itself.”)(citing United States ex rel. Kirk, 563 U.S. 401, 407 (2011)). When considering the language Congress employs, a court “read[s] the words of the statute in their context and with a view to their place in the overall statutory scheme,” and thereby “ordinarily resist reading words or elements into a statute that do not appear on its face.” United States v. Sturm, 673 F.3d 1274, 1279 (10th Cir. 2012). See Hughes Aircraft Co. v. Jacobson, 525 U.S. 432, 438 (1999)(“As in any case of statutory construction, our analysis begins with the language of the statute. And where the statutory language provides a clear answer, it ends there as well.”). Generally, it is the duty of the court “to give effect, if possible, to every clause and word of a statute.” Duncan v. Walker, 533 U.S. 167, 174 (2001)(quoting United States v. Menasche, 348 U.S. 528, 538-39 (1955)). The Supreme Court of the United States of America has therefore expressed its “‘reluctan[ce] to treat statutory terms as surplusage’ in any setting.” Duncan v. Walker, 533 U.S. at 174 (quoting Babbitt v. Sweet Home Chapter, Cmty. for a Great Ore., 515 U.S. 687, 698 (1995)). See Bridger Coal Co./Pac. Minerals, Inc. v. Dir., Office of Workers’ Compensation Programs, 927 F.2d 1150, 1153 (10th Cir. 1991)(“We will not construe a statute in a way that renders words or phrases meaningless, redundant, or superfluous.”).

“A statute is ambiguous when it is ‘capable of being understood by reasonably well-informed persons in two or more different senses.’” United States v. Quarrell, 310 F.3d 664, 669 (10th Cir. 2002)(quoting In re Geneva Steel Co., 281 F.3d at 1178). “The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole.” Ceco Concrete Const., LLC v. Centennial State Carpenters Pension Tr., 821 F.3d 1250, 1258 (10th Cir. 2016)(quoting Robinson v. Shell Oil Co., 519 U.S. 337, 341 (1997)). If statutory meaning cannot be derived “merely by reference to the text,” a court “may also look to traditional canons of statutory

construction to inform our interpretation,” Conrad v. Phone Directories Co., 585 F.3d 1376, 1381 (10th Cir. 2009), and “may seek guidance from Congress’s intent, a task aided by reviewing the legislative history,” In re Geneva Steel Co., 281 F.3d at 1178. “Ambiguous text can also be decoded by knowing the purpose behind the statute.” In re Geneva Steel Co., 281 F.3d at 1178.

The Court begins by walking through § 1501.2(a)’s text to see how it should be read and to see where the ambiguity exists. Section 1502(a)’s first sentence is not ambiguous: § 1501.2(a) states that the small parts regulation, § 1500.18(a)(9), “applies to all toys and other articles intended for use by children under 3 years (36 months) of age” 16 C.F.R. § 1501.2(a). This first sentence means that, if a toy, such as the Calico Critters Yellow Labrador Twins toy here, is intended for use by children under three, it cannot have a small part, as an accessory or as a part that breaks off after the use and abuse testing, that presents an aspiration, choking, or ingestion hazard. See 16 C.F.R. §§ 1500.18(a)(9), 1501.2, 1501.4, 1500.51(c), 1500.52(c). The parties’ dispute arises from how to determine whether a toy is “intended for use by children under 3 years (36 months) of age.” 16 C.F.R. § 1501.2(a).

Under the first interpretation, the three-factor § 1501.2(b) test is used for every toy, because § 1501.2(a) states that the small parts regulation “applies to all toys and other articles intended for use by children under 3 years (36 months) of age,” 16 C.F.R. § 1501.2(a), and in § 1501.2(b), the regulation explains how to “determine[e] which toys and other articles are intended for children under 3 (36 months of age,” 16 C.F.R. § 1501.2(b). Read together, it is logical to turn to the three-factor § 1501.2(b) test as the primary method to determine whether a toy is intended for use by children under three years old, because it states how to make the required determination. Under the first interpretation, then, it is not dispositive whether a toy is enumerated in the non-exhaustive

list of nineteen types of toys, but a general example⁵⁸ to consider, because § 1501.2(a) does not

⁵⁸The CPSC’s website describes the § 1501.2(a) list as a list of “general examples.” Small Parts for Toys and Children’s Products Business Guidance, United States Consumer Product Safety Commission, <https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Small-Parts-for-Toys-and-Childrens-Products> (last visited April 19, 2021)(emphasis in the original). The Court takes judicial notice of the CPSC’s website, because an agency’s website is a matter of public record and a “source[] whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b). See Fed. R. Evid. 201(f); Leon v. Fedex Ground Package Sys., Inc., 163 F. Supp. 3d 1050, 1066 (D.N.M. 2016)(Browning, J.). An agency document, although lacking the force of law and not entitled to Chevron v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984), deference, may be given respect according to its persuasiveness under Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)(“Skidmore”). Under Skidmore, if a federal regulation is ambiguous, the question is whether the agency guidance has “the power to persuade.” Skidmore, 323 U.S. at 140. See Carpio v. Holder, 592 F.3d 1091, 1098 (10th Cir. 2010)(“The paramount consideration is whether the BIA’s decision has ‘the power to persuade.’”)(quoting Skidmore, 323 U.S. 134, 140 (1944)). The Court will give the agency interpretation “weight . . . depend[ing] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.” Skidmore, 323 U.S. at 140. See United States v. Mead Corp., 533 U.S. 218, 221, 228 (2001)(explaining that, under Skidmore, the degree of deference given informal agency interpretations will “vary with circumstances, and courts have looked to the degree of the agency’s care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency’s position”). See, e.g., Hernandez v. Grisham, No. CIV 20-0942 JB/GBW, 2020 WL 7481741, at *68 (D.N.M. Dec. 18, 2020)(Browning, J.)(analyzing four guidance documents from the United States Department of Education under Skidmore); N. New Mexico Stockman’s Ass’n v. United States Fish & Wildlife Serv., No. CIV 18-1138 JB/JFR, 2020 WL 6048149, at *76 (D.N.M. Oct. 13, 2020)(Browning, J.)(concluding that, “although Chevron does not apply, [the agency,] Fish & Wildlife is entitled to some deference under Skidmore . . .”).

On the CPSC’s website, under the header “Small Parts for Toys and Children’s Products Business Guidance,” the CPSC states the § 1501.2(a) “lists general examples” and that the “rule” to determine whether a toy is intended for use by children under three relies on the three-factor § 1501.2(b) test:

What is the purpose of a small parts regulation?

This regulation prevents deaths and injuries to children under three from choking on, inhaling, or swallowing small objects they may “mouth”. It bans toys and other articles that are intended for use by children under three and that are or have small parts, or that produce small parts when broken.

Which products must meet this regulation?

state that the non-exhaustive list is dispositive. Furthermore, the Court can imagine a situation, as the Defendants contend here, where a toy matches some characteristic listed in § 1501.2(a), but all the other factors -- the label, the advertising, the promotion, the marketing, and the common recognition -- strongly suggest that the toy is not for use by children under three. In this situation, the fact that the toy at issue aligns with the non-exhaustive is a factor to consider whether the label is reasonable and how the toy is commonly recognized. For example, if the evidence shows that a toy is a flocked toy, then such evidence could be used to show that a 3+ label is not reasonable and that the toy is commonly recognized for use by children under three years of age; however,

The regulation covers products that are intended for use by children under three. These products include a wide range of articles such as toys, dolls, and puzzles, nursery equipment, infant furniture and equipment such as playpens, strollers, and baby bouncers and exercisers. See 16 C.F.R. Part 1501.2 for a more detailed list.

....

How can manufacturers determine what toys and other products are “intended for” use by children under 3 years?

The rule lists general examples of the types of products that are intended for use by children under 3 years old. 16 C.F.R. 1501.2(a)

To determine whether a toy is intended for use by children under three: the manufacturer’s stated intent, such as the age stated on a label; the advertising, promotion, and marketing of the product as being intended for use by children of a certain age; and whether the product or toy is commonly recognized as being intended for use by children under 3 years old. See 16 C.F.R. 1501.2(b).

Small Parts for Toys and Children’s Products Business Guidance, United States Consumer Product Safety Commission, <https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Small-Parts-for-Toys-and-Childrens-Products> (last visited April 19, 2021)(emphasis in the original). Although, the CPSC’s website for regulatory information states that the § 1501.2(a) list provides “general examples,” the Court concludes that the CPSC’s small parts webpage is cursory and provides no substantive explanation of the regulation, and is not entitled to any Skidmore deference, because the webpage contains no thorough analysis and therefore has no power to persuade. See Carpio v. Holder, 592 F.3d at 1098.

under this first interpretation, the fact that a toy is flocked is not dispositive, rather the three-factors are weighed together. Further, under the three-factor test, if the toy is intended solely for use by children older than three years of age, then the small parts regulation does not apply. See 16 C.F.R. § 1501.2(c).

Under the second interpretation, advanced by the Plaintiffs, there are two steps to determine whether the toy at issue is intended for use by children under three years of age and therefore subject to the small parts regulation. Section 1501.2(a) provides a non-exhaustive list of nineteen “such” toys “intended for use by children under 3 years (36 months) of age” to which the small parts regulation, § 1500.18(a)(9), applies. 16 C.F.R. § 1501.2(a). This non-exhaustive list is divided into two parts, first a list fourteen toys, with no descriptive qualifier --

squeeze toys; teethingers; crib exercisers; crib gyms; crib mobiles; other toys or articles intended to be affixed to a crib, stroller, playpen, or baby carriage; pull and push toys; pounding toys; blocks and stacking sets; bathtub, wading pool and sand toys; rocking, spring, and stick horses and other figures; chime and musical balls and carousels; jacks-in-the-box; stuffed, plush, and flocked animals and other figures

-- and second, a list of five toys with the qualifier “intended for use by children under 3” --

preschool toys, games and puzzles intended for use by children under 3; riding toys intended for use by children under 3; infant and juvenile furniture articles which are intended for use by children under 3 such as cribs, playpens, baby bouncers and walkers, strollers and carriages; dolls which are intended for use by children under 3 such as baby dolls, rag dolls, and bean bag dolls; toy cars, trucks, and other vehicles intended for use by children under 3.

16 C.F.R. § 1501.2(a). The first step is, therefore, to determine whether the toy at issue is one of the enumerated toys, i.e., is it either one of the fourteen toys that does not have the “intended for use by children under 3” qualifier, or is it one of the five toys with the “intended for use by children under 3” qualifier. 16 C.F.R. § 1501.2(a). The first set of fourteen types of toys, e.g., “teethers,” are categorically for use by children under three years of age, whereas, the second set of five types of toys, e.g., “toy cars,” are not categorically for use by children under three years of age, because

they require a determination that the toy is “intended for use by children under 3.” 16 C.F.R. § 1501.2(a). For the second set of toys, to determine whether a toy is “intended for use by children under 3,” § 1501.2(b) provides three factors:

In determining which toys and other articles are intended for use by children under 3 years (36 months) of age, for purposes of this regulation, the following factors are relevant: the manufacturer’s stated intent (such as on a label) if it is a reasonable one; the advertising, promotion, and marketing of the article; and whether the article is commonly recognized as being intended for children under 3.

16 C.F.R. § 1501.2(b). If the toy at issue matches one of the enumerated types of toys, then the toy satisfies the requirements of § 1501.2, and it is categorically intended for use by children under three years old. The second step, if the toy at issue is not within the non-exhaustive list of nineteen toys, is to apply the general test, which § 1501.2(a) provides: “In addition, such articles include any other toys or articles which are intended, marketed or labeled to be entrusted to or used by children under 3 years of age.” 16 C.F.R. § 1501.2(a). Here again, the three-factor § 1501.2(b) test applies to determine whether the toy is intended for use by children three years of age, because the general test in § 1501.2(a) uses the language of the three factor § 1501.2(b) test. See 16 C.F.R. § 1501.2(a) (stating that, in addition to the list, toys include those “intended . . . to be . . . used by children under 3 years of age.”). If the toy at issue is not included in either of the two steps, the toy is not subject to the small parts regulations, because it is not intended for children under three years of age. See 16 C.F.R. § 1501.2(c). The Second Circuit supports this interpretation:

First, we note that the non-exclusive listing of “covered products” provides a reasonable degree of guidance in assessing many articles (e. g., certain products, although not specifically enumerated, can easily be determined to belong to the broad category of “crib” toys, toys which obviously are intended for children under three years of age). To the extent that it remains uncertain whether an “unlisted” article falls within the coverage of the Small Parts Regulation, we believe that application of the three non-determinative criteria will resolve the issue satisfactorily in most, if not in all, cases. Although ranking or weighting of these criteria might produce an added degree of certainty, the CPSC’s reluctance to take such action is understandable in view of former instances involving the mislabeling of articles clearly intended for children under three years of age.

Toy Mfrs. of Am., Inc. v. Consumer Prod. Safety Comm'n, 630 F.2d at 78 (footnote omitted).⁵⁹

The ambiguity arises, because § 1501.2 does not clearly lay out this two-step process, and § 1501.2 uses the language “intended for use by children under 3” five times: (i) it is used in the first sentence of § 1501.2(a), which states the small parts regulation “applies to all toys and other articles intended for use by children under 3 years (36 months) of age . . .”; (ii) it is used to qualify some toys, e.g., “preschool toys, games and puzzles intended for use by children under 3”; (iii) it is used in a general test, “such articles include any other toys or articles which are intended . . . to be . . . used by children under 3 years of age”; (iv) in the three-factor test, “[i]n determining which toys and other articles are intended for use by children under 3 years (36 months) of age, for purposes of this regulation, the following factors are relevant . . .”; and (v) and it is used to explain that the “[t]his regulation does not apply to toys or articles which are solely intended for use by children 3 years of age or older.” 16 C.F.R. § 1501.2(a)-(c). Because § 1501.2 repeats the intended for use by children language multiple times, it is not evident for what purpose the three-factor test properly is considered -- whether it is used only to determine whether a toy is one of the five enumerated toys with the qualifier “intended for use by children under 3” or whether the test used

⁵⁹The Second Circuit concludes that the small parts regulation is not “impermissibly vague” under the “Fifth Amendment’s due process proscription against unreasonably vague criminal statutes.” Toy Mfrs. of Am., Inc. v. Consumer Prod. Safety Comm’n, 630 F.2d at 77, 79. The Second Circuit’s conclusion is unsurprising, because when a statute or regulation is challenged as void for vagueness, courts afford great latitude to a statute or regulation enacted to protect public health and safety; the standard requires only that the meaning of the statute or regulation be discoverable from its context, or even by resorting to an administrative process. See Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498 (1982). The Second Circuit’s conclusion that § 1501.2 is not vague does not imply that the regulation is not ambiguous, because a different standard applies. See Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. at 498 (“The degree of vagueness that the Constitution tolerates . . . depends in part on the nature of the enactment. Thus, economic regulation is subject to a less strict vagueness test because its subject matter is often more narrow, and because businesses, which face economic demands to plan behavior carefully, can be expected to consult relevant legislation in advance of action.”).

for every toy. Section 1501.2 is therefore ambiguous, because the regulation suggests that there are two general tests: (i) “[i]n addition, such articles include any other toys or articles which are intended, marketed or labeled to be entrusted to or used by children under 3 years of age,” 16 C.F.R. § 1501.2(a), and (ii) “[i]n determining which toys and other articles are intended for use by children under 3 years (36 months) of age, for purposes of this regulation, the following factors are relevant: . . . ,” 16 C.F.R. § 1501.2(b). The first test is used in conjunction with the non-exhaustive list, but the regulation does not specify whether the three-factor test is still used for this inquiry, or whether the two tests employ the same standard or a different standard. Further, § 1501.1 explains that § 1501.2 “describes certain articles that are subject to § 1500.18(a)(9),” whereas § 1501.3 “lists certain articles that are specifically exempted.”⁶⁰ 16 C.F.R. § 1501.1.

⁶⁰Section 1501.3 provides a specific list of “articles are exempt from this regulation (§§ 1500.18(a)(9) and 1501.4 below):

- (a) Balloons;
- (b) Books and other articles made of paper;
- (c) Writing materials such as crayons, chalk, pencils, and pens;
- (d) Children’s clothing and accessories, such as shoe lace holders and buttons;
- (e) Grooming, feeding, and hygiene products, such as diaper pins and clips, barrettes, toothbrushes, drinking glasses, dishes and eating utensils;
- (f) Phonograph records;
- (g) Modeling clay and similar products;
- (h) Fingerpaints, watercolors, and other paint sets;
- (i) Rattles (as defined at 16 CFR 1510.2); and
- (j) Pacifiers (as defined at 16 CFR 1511.2(a)).

16 C.F.R. § 1501.3.

Section 1501.1 suggests therefore that there is a distinction between the more general description found in § 1501.2 and the specific list found in 1501.3. The Court concludes, therefore, that § 1501.2 is ambiguous.

B. BECAUSE § 1501.2 IS AMBIGUOUS, THE COURT TURNS TO THE LEGISLATIVE HISTORY, WHICH INDICATES THAT ANY TOY LISTED IN § 1501.2(a) IS DEFINITELY INTENDED FOR USE BY CHILDREN UNDER THREE YEARS OF AGE.

Because § 1501.2 can be read reasonably in two ways, and is therefore ambiguous, see United States v. Quarrell, 310 F.3d at 669; In re Geneva Steel Co., 281 F.3d at 1178, the Court “may seek guidance from Congress’s intent, a task aided by reviewing the legislative history,” In re Geneva Steel Co., 281 F.3d at 1178. “Ambiguous text can also be decoded by knowing the purpose behind the statute.” In re Geneva Steel Co., 281 F.3d at 1178. After considering the legislative history, the Court concludes that any toy listed in § 1501.2(a) is intended definitively for use by children under three years of age, and that the three-factor § 1501.2(b) test is used to determine whether a toy that is not listed in § 1501.2(a) is intended for use by children under three years of age.

In 1979, the CPSC, in the Federal Registrar when it promulgated its final rule, explains the background of the small parts regulation:

The Commission regulates the safety of toys and other children’s articles under the Federal Hazardous Substances Act (FHSA, 15 U.S.C. 1261 et seq.). Before the Commission began operating in May 1973, the Food and Drug Administration (FDA) regulated toy safety under FHSA authority.

In 1970 the FDA issued two toy safety regulations which addressed the aspiration, ingestion, and choking hazards presented by particular small parts in toys, such as noisemaking components in rattles (these regulations are now codified with the Commission’s regulations at 16 CFR 1500.18(a)(1) and (2)). Under the authority of these regulations, the FDA and later the Commission took many actions against particular toys which contained loose, small objects that could injure children.

In January 1973 the FDA proposed for public comment a comprehensive

regulation designed to (1) identify toys and other articles intended for use by children under 3 years of age which present a mechanical hazard from small parts, (2) identify mouth-actuated toys intended for use by children under 8 years of age which present a mechanical hazard from small parts, and (3) classify all such products as "banned hazardous substances" under the FHSA (38 FR 2179-80, Jan. 22, 1973).

The January 1973 proposed regulation used a truncated, hollow cylinder of specified dimensions to determine which products were too small (or had components that were too small). In addition, the proposal referenced "use and abuse" test procedures to simulate the "normal use" and "reasonably foreseeable damage or abuse" which are part of the statutory definition of a mechanical hazard (section 2(s) of FHSA, 15 U.S.C. 1261(s)).

Some products which are normally intended by the manufacturer for children over 3 years of age may not be readily recognized by the purchaser as potentially unsuitable for younger children due to the presence of small parts. The FDA proposal therefore provided an exemption for those products only if they had the "negative" label "Caution: Not Recommended for Children Under 3 Years Old." A similar exemption based on cautionary negative labeling was proposed for mouth actuated toys "not generally recognized as being suitable for use only by children 8 years of age or older." The proposal contained additional exemptions for chalk, crayons, and books made entirely from paper because the FDA believed the developmental benefits that children derive from the use of these products outweigh the potential danger of their being aspirated or ingested.

In response to its proposal, the FDA received over 90 comments from manufacturers, distributors, trade associations, the American Academy of Pediatrics, and individual consumers. Many of these comments were extensive and extremely critical. They addressed: the very broad and undefined scope of the regulation; the lack of documentation for establishing the size and configuration of the test device; the vagueness of the labeling provisions and the exaggerated size requirements of lettering; the adverse effect of negative labeling; and the adequacy of lead time for compliance. In addition, the comments included requests for 20 different product class exemptions.

On October 16, 1978 the Commission proposed for public comment a revised small parts banning regulation (43 FR 47684-88). In this revised proposal, the Commission took into account the comments received in response to the FDA's January 1973 proposal.

Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts, 44 Fed. Reg. 34892-93 (June 15, 1979)(citing and discussing Classification as Banned Hazardous

Substances of Certain Toys and Other Articles Presenting Mechanical Hazards Due to Small Parts, 43 Fed. Reg. 47685-87 (October 16, 1978)). In the Federal Register, the CPSC then explained § 1501.2's scope:

As proposed, the small parts regulation applied to nearly all toys and other articles intended for children under 3 years of age. All children and adults are potential victims of the hazard presented by small parts, but children under 3 are particularly susceptible.

Children under 3 indiscriminately put things into their mouths and do not have the knowledge of cause and effect relating to protecting themselves from potential hazards as does an older child or adult. (This is discussed fully in an April 17, 1978 staff report, entitled "Normal Developmental Behavior in Young Children and Their Relationship to Potential Hazards," which is available from the Office of the Secretary.) In addition, very small parts on toys that are intended for use by children under 3 usually serve a limited or no functional purpose. Finally, it is easier to control the products to which children under 3 have access than to control the products to which older children have access. Children under 3 could, of course, encounter and choke on a coin, hairpin, or other adult item or on toys intended for use by their older brothers and sisters. However, the Commission's proposal was based on its belief that a regulation directed at toys intended to be used by children under 3 will have a positive impact in reducing injuries.

In determining which toys and other articles are intended for children under 3, the Commission proposed to consider such factors as the manufacturer's stated intent (such as on a label) if it is a reasonable one; the advertising, promotion, and marketing of the toy; and whether the toy is commonly recognized as being intended for children under 3. As proposed, none of these factors would necessarily be determinative. (It should be noted that products which are intended both for children under 3 and for older children would fall within the scope of the regulation.)

The proposed regulation covered all toys and other articles intended for use by children under 3 that were included in a long list of product categories. The list was developed from a number of sources including the Toy Manufacturers of America classification system, published commercial promotional materials, and a retail store survey conducted by the Commission staff. While this list was not intended to be exhaustive, the Commission believed that the vast majority of toys covered by the regulation would fall within at least one of these categories. Because of the very broad scope of the proposed regulation, the Commission expected the list of product categories to help industry representatives and consumers focus on the products being regulated. The Commission emphasized that, even if a toy did not fall within a category on the list, it would be covered by the regulation as long as it is intended for use by children under 3 and is not specifically excluded from coverage.

The Commission proposed exemptions for a number of products whose functional, educational, or other value outweigh any possible hazard from small parts. In some cases, compliance with the small parts regulation would mean drastic redesign of useful everyday products at substantial cost to the consumer. In other cases, compliance would be physically impossible because the product could not perform its function if redesigned.

44 Fed. Reg. 34893-95 (emphasis added). In its discussion of the public comments it had received in response to the proposed rule, the CPSC reiterated:

Products covered by regulation.

Many commenters have expressed views about the scope of the small parts regulation. A recurring, comment from the toy industry was that the regulation does not clarify which toys and other articles are “intended for use by children under 3 years of age.”

When proposing the small parts regulation in October 1978 the Commission provided a specific list of the toys which are covered. The Commission also listed the factors it would consider before determining which other toys might be intended for children under 3. As summarized above in the Scope section under Proposed Regulation (section III, C), these factors include the manufacturer’s stated intent (such as on a label) if it is a reasonable one; the advertising, promotion, and marketing of the toy; and whether the toy is commonly recognized as being intended for children under 3.

Since none of the factors is determinative, many toy manufacturers expressed the concern that they will not know for certain whether their toys are covered by the regulation. Therefore, many suggested that the manufacturer’s labeling should be conclusive on the question of whether a toy is intended for children under 3.

The Commission made a special effort to define clearly the scope of the small parts proposed regulation. The scope section (1501.2) included a lengthy list of the types of products that are definitely covered. This list was based on the Commission staff’s retail survey of toys and children’s articles. The Commission believes that this list covered most products which might reasonably be intended for children under 3.

The nature of any broad, generic regulation is that a few products will not be conclusively included in or excluded from the defined class. Therefore, the Commission has indicated factors to help determine fairly which “borderline” products might be covered by the regulation.

No single factor can determine conclusively whether a borderline toy is intended for children under 3. The manufacturer’s labeling is undoubtedly one

factor. If a toy's carton recommends "For children ages 2-5," it is likely that purchasers of that toy will give it to children of those ages. However, it is also likely that some purchasers will buy the toy for precocious children who are only one-and-one-half years old. Thus, despite the labeling, such a toy will actually be used by children for whom the manufacturer apparently does not intend it.

Similarly, the ways in which toys are packaged, promoted, and otherwise marketed will be factors in determining the age group for which they are intended. As an example, an exclusive import shop might be selling an expensive collector's item for adults or older children. A toy store might be selling inexpensive imitations of this item as toys for young children. In this example, place of sale and price would be important factors. The type and manner of advertising might also be factors.

Most marketing factors cannot be conclusive in determining whether a toy is intended for children under 3. Using the collector's item example, what would be the price cut-off and what would be the definitive description of what is an import shop and what is a toy store? In order to write a rule in which specific marketing factors clearly separated toys intended for children under 3 from all other products, the Commission would have to disregard many subtle but relevant factors.

If the manufacturer's intent as stated on a label were solely determinative, hazardous toys that are genuinely intended for children under 3 could be intentionally or unintentionally mislabeled to fall outside of the Commission's small parts regulation.

Another deficiency with making labeling the sole and conclusive factor is that there are no industry-wide guidelines on age labeling. Consumers must contend with the differing practices of individual manufacturers. The Commission has observed at least one extreme example of how much these practices differ. On one page of a newspaper advertising supplement, a major toy retailer pictured and described a number of "baby dolls". In essence, these were the same dolls but were made by different companies. The manufacturers' age recommendations, which were also noted, were 3-8, 3-9, 21-up, 3-10, 3-up, 2-7, 1-7, and 2-9. Nevertheless, the Commission has every reason to believe that these baby dolls are all appropriate for use by children in the same age group.

The Commission believes that many factors are relevant to the determination of whether particular toys are intended for children under 3 and that none of these factors can be conclusive in isolation. In addition, manufacturers are not powerless to affect the marketing of their toys and are not ignorant of the way their toys are actually marketed.

Because of the importance of the factors, the Commission has decided to incorporate them into the small parts regulation. (They were discussed in the preamble to the small parts proposal.) Section 1501.2(b) of the final regulation below reflects this change.

The factors are most meaningful when they are carefully applied to the particular toys involved. Under a recently-amended procedure, the Commission's compliance and enforcement staff will be required to do this in every case, before initiating any enforcement action under the small parts regulation. The Commission believes that the scope of its small parts regulation is sufficiently clear. However, many commenters from the industry disagree. The procedure, along with the Commission's willingness to entertain requests for advice about the coverage of specific toys, addresses the strongly stated industry comments that some toys are not clearly included in or excluded from the regulation.

44 Fed. Reg. 34897-98 (*italics in the original, underline added*).

Although, when proposing the small parts regulation in 1978, the CPSC did not state that any toy listed in § 1501.2(a) was definitively covered, see 43 Fed. Reg. 47685,⁶¹ in its notice of final agency regulation in 1979, when it responds to the public comments to the proposed rule, the CPSC describes § 1501.2(a)'s list as “a specific list of the toys which are covered,” and as a “lengthy list of the types of products” that all “definitely covered.” 44 Fed. Reg. 34897. The CPSC explains that it “believes that this list covered most products which might reasonably be intended for children under 3.” 44 Fed. Reg. 34897. The CPSC came to this conclusion, because

⁶¹In 1978, in its notice of proposed regulation, the CPSC was not as clear about the standard as it is in 1979. See 43 Fed. Reg. 47685. In its notice of proposed regulation, the CPSC first discusses the three-factor test, before discussing the non-exhaustive list, and stops short of stating that if a product falls within the list, then that inclusion is dispositive of the inquiry. See 43 Fed. Reg. 47685. Rather, the CPSC's discussion suggests that the list is descriptive and “helpful to industry representatives and to consumers” to put them on notice of to what “categories” of toys the regulation applies:

The proposed regulation covers all toys and other articles intended for use by children under 3 that are included in a long list of product categories (§1501.2). While this list is not intended to be exhaustive, the Commission believes that the vast majority of toys covered by the regulation will fall within at least one of these categories. Because the scope of the proposed regulation is very broad, the list of product categories should be helpful to industry representatives and to consumers who want to focus on the products that the Commission intends to regulate.

43 Fed. Reg. 47685. The following year, however, in its notice of its final regulation, the CPSC clarifies its position that any toy listed in § 1501.2(a) is “definitively” covered. 44 Fed. Reg. 34897.

it studied “the Toy Manufacturers of America classification system, published commercial promotional materials, and a retail store survey conducted by the Commission staff,” which indicated that these types of toys are attractive to children under three years of age. 44 Fed. Reg. 34894.⁶² The CPSC also explains that the three-factor § 1501.2 test “help[s] determine fairly which ‘borderline’ products might be covered by the regulation.” 44 Fed. Reg. 34897 (no citation for quotation). The CPSC states that, “even if a toy did not fall within a category on the list, it would be covered by the regulation as long as it is intended for use by children under 3 and is not

⁶²The Court concludes that the interpretation that every toy listed in § 1501.2(a) is intended definitively for use by children under three years of age does not lead to an absurd result, because each of the listed toys is conceivably attractive to children younger than three years of age. See Robbins v. Chronister, 435 F.3d 1238, 1241 (10th Cir. 2006)(“This court has said that an interpretation of a statute is absurd if it leads to “results so gross as to shock the general moral or common sense.”)(quoting United States v. Newsome, 898 F.2d 119, 121 n. 3 (10th Cir. 1990)). For instance, “squeeze toys; teething; crib exercisers; crib gyms; crib mobiles; other toys or articles intended to be affixed to a crib, stroller, playpen, or baby carriage” are all toys targeting infants. 16 C.F.R. § 1501.1(a). See Good Toys for Young Children by Age and Stage, The National Association for the Education of Young Children, <https://www.naeyc.org/resources/topics/play/toys> (last visited April 22, 2021)(listing “[t]hings they can reach for, hold, suck on, shake, make noise with -- rattles, large rings, squeeze toys, teething toys, soft dolls, textured balls, and vinyl and board book” as ideal toys for children birth through six months old). And “pounding toys” and “blocks and stacking sets” help with muscle control development for young children. 16 C.F.R. § 1501.1(a). See Good Toys for Young Children by Age and Stage (listing things to drop and take out and things to use their muscles with, including push and pull toys as ideal for children under one years of age). It does not “shock . . . common sense,” Robbins v. Chronister, 435 F.3d at 1241, that the other toys -- “bathtub, wading pool and sand toys; rocking, spring, and stick horses and other figures; chime and musical balls and carousels; jacks-in-the-box; stuffed, plush, and flocked animals and other figures” -- are conceivably attractive to younger children, 16 C.F.R. § 1501.1(a). See Good Toys for Young Children by Age and Stage (listing toys for children under three years old). The Second Circuit supports the Court’s conclusion:

The fact that articles are covered, not all of whose intended users are under three years of age, although admittedly broadening the range of articles covered, does not add measurably to the difficulty in identifying whether a particular article is within the scope of coverage of the Small Parts Regulation.

Toy Mfrs. of Am., Inc. v. Consumer Prod. Safety Comm’n, 630 F.2d at 78 n.17.

specifically excluded from coverage.” 44 Fed. Reg. 34894. The CPSC explains why relying on labeling is not preferred: “If the manufacturer’s intent as stated on a label were solely determinative, hazardous toys that are genuinely intended for children under 3 could be intentionally or unintentionally mislabeled to fall outside of the Commission’s small parts regulation.” 44 Fed. Reg. 34897. The legislative history, therefore, supports the conclusion that the § 1501.2(a) list is dispositive, and that the three-factor § 1501.2(b) test is “help[ful]” to determine whether a toy that is not enumerated on the non-exhaustive list is intended for use by children under three years of age. 44 Fed. Reg. 34897.

Accordingly, the Court concludes that, because it is undisputed that the Calico Critters Yellow Labrador Twins toy is a flocked toy -- a toy listed in § 1501.2(a) -- it is “intended for use by children under three years (36 months) of age” as a matter of law. 16 C.F.R. § 1501.2(a). Furthermore, because it is undisputed that the Calico Critters Yellow Labrador Twins toy has small parts that “present[] a choking, aspiration, or ingestion” hazard, the Calico Critters Yellow Labrador Twins toy violates § 1500.18(a)(9) as a matter of law. 16 C.F.R. § 1500.18(a)(9) (“Any toy or other article intended for use by children under 3 years of age which presents a choking, aspiration, or ingestion hazard because of small parts as determined by Part 1501 of this chapter and which is introduced into interstate commerce after January 1, 1980.”).

C. EVEN IF THE COURT CONSIDERS THE § 1501.2(b) FACTORS, THE COURT WOULD DENY THE MSJ, BECAUSE QUESTIONS OF FACT EXIST WHETHER § 1501.2(B)’S THREE FACTORS ARE SATISFIED, INCLUDING WHETHER THE LABEL IS REASONABLE, WHETHER THE CALICO CRITTERS YELLOW LABRADOR TWINS TOY WAS MARKETING TO CHILDREN UNDER THREE, AND HOW THE TOY IS COMMONLY RECOGNIZED.

Although the Court concludes that the Calico Critters Yellow Labrador Twins toy violates the small parts regulation as a matter of law, because it is undisputed that the toy is flocked and has small parts, the Court would nonetheless deny the MSJ if it were to consider the three-factor

§ 1501.2(b) test. To prevail under the § 1501.2(b) test on summary judgment, Epoch Everlasting must show that there is no factual dispute that (i) “the manufacturer’s stated intent,” including the 3+ label, is reasonable; (ii) “the advertising, promotion, and marketing of the article” targeted solely children older than three years old; and (iii) the toy is not “commonly recognized as being intended for children under 3.” 16 C.F.R. § 1501.2(b). Because Epoch Everlasting bears the burden and there is a factual dispute as to each of the three elements, Epoch Everlasting does not prevail under the § 1501.2(b) test.

To support its conclusion that “the Yellow Labrador Twins are intended for use by children ages 3 and up,” MSJ at 7, Epoch Everlasting does not address the three § 1501.2(b) factors individually; instead, Epoch Everlasting explains that a third-party certification company and their expert conclude that the toy is intended for ages three and up:

Epoch [Co.] designed the product, its packaging and had it tested for safety by an independent company. Those test results all certified that the Yellow Labrador Twins were safe for use by children ages 3 and up. . . . EEP’s expert Dr. Carol Pollack-Nelson age graded the Yellow Labrador Twins . . . based on the four factors in the CPSIA: (1) the manufacturer’s stated intent and the reasonableness of the manufacturer’s age grade; (2) the marketing, advertising, promotion and display of the product; marketed to children younger than 3 years of age; and (4) the 2002 CPSC Age Determination Guidelines. Based on these four factors, Dr. Pollack-Nelson determined the product Ms. Dedios purchased for her two-and-a-half-year-old daughter was intended for children ages 3 and up.

MSJ at 8-9. Epoch Everlasting contends that the fact that “the product is flocked is irrelevant because Part 1501 does not apply to products intended for children ages 3 and up.” MSJ at 8. The Plaintiffs, in response, point to their experts who come to the opposite conclusion. See MSJ Response at 20, 20 n.13 (citing Declaration of Dennis B. Brickman at 101 (dated January 12, 2021), filed January 15, 2021 (Doc. 119-15)(“Brickman Decl. and Report”)(“The age grading by the manufacturer of 3+ on the subject product package is not reasonable.”);⁶³ Declaration of Joe

⁶³The Court’s citations to the Brickman Decl. and Report uses the CM/ECF page numbers.

Mohorovic at 25 (dated January 12, 2021), filed January 15, 2021 (Doc. 119-11)(“Mohorovic Decl. and Report”)(“The subject products were labelled ‘3+’ and ‘Not for children under 3 years.’ This is the manufacturer’s stated intent, but it is not reasonable.”)).⁶⁴

Although Epoch Everlasting leans heavily on its arguments that: (i) an independent testing company certified the Calico Critters Yellow Labrador Twins toy; and (ii) that its expert concludes that the toy is meant for children older than three years. See MSJ at 7-9. Epoch Everlasting’s summary conclusion that the Calico Critters Yellow Labrador Twins toy meets the §§ 1500.18(a)(9) and 1501.2 requirements is, however, without evidentiary basis, and is therefore not sufficient at summary judgment: Epoch Everlasting must assert undisputed facts that address each of the three § 1501.2(b) factors. See 16 C.F.R. § 1501.2(b). Epoch Everlasting can use its experts to create a factual basis to argue that there is no dispute that the toy satisfies the three-factor § 1501(b) test, see United States v. Richter, 796 F.3d at 1195; United States v. Bedford, 536 F.3d 1148, 1158 (10th Cir. 2008); however, Epoch Everlasting, in its recitation of undisputed facts, only lists one relevant undisputed fact: that the Yellow Labrador Twins toy was labeled for children ages three and up. See MSJ ¶ 2, at 3. Epoch Everlasting does not provide any facts relevant to whether the 3+ label “is a reasonable one;” whether “the advertising, promotion, and marketing of the article” target children under three years of age; or “whether the article is commonly recognized as being intended for children under 3” years of age. 16 C.F.R. § 1501.2(b). See MSJ ¶¶ 1-6, at 3-4. A label, however, is not dispositive whether a toy is intended for use by a certain age range, because the label must be reasonable. See 16 C.F.R. § 1501.2(b). See also Toy Mfrs. of Am., Inc. v. Consumer Prod. Safety Comm’n, 630 F.2d at 78 (concluding

⁶⁴The Court’s citations to the Mohorovic Decl. and Report uses the CM/ECF page numbers.

that “no one of these criteria will be considered dispositive”). Cf. 16 C.F.R. § 1200.2(c)(1) (“The manufacturer’s label, in and of itself, is not considered to be determinative.”). In her report, Epoch Everlasting’s expert Dr. Pollack-Nelson, concludes that the label is “conspicuous[],” and that “market review . . . revealed that” products similar to the Calico Critters Yellow Labrador Twins toy “are typically age graded for 3+,” but does not state explicitly that the label is reasonable. Age Determination: Calico Critters -- Yellow Labrador Twins September 25, 2020, at 8, 51, filed January 15, 2021 (Doc. 121-9)(“Pollack-Nelson Report”).⁶⁵ In her deposition, Dr. Pollack-Nelson agreed that “even large and conspicuous warnings are often overlooked,” and that “warnings are not a substitute for safe design.” Pollack-Nelson Depo. at 98:23-99:4.⁶⁶ In his report, Brickman concludes that the 3+ label is not reasonable:

Given that both Calico Critters and Sylvanian Families product packages have been previously labeled 4+ (including the Golden Labrador Twins), even the manufacturer and supplier indicate that Calico Critters are not reasonably safe for 3 year olds, which is a further contradiction to the Calico Critters website FAQs (children less than 2 years old) and an indication that Calico Critters are intended for children of all ages. Further, this 4+ age grade previously provided on packages for Calico Critters and Sylvanian Families is inconsistent with the age grade of 3+ listed on the SGS test reports for the Calico Critters Yellow Labrador Twins and accessories product. The manufacturer’s stated intent for the age grading is only relevant if it is reasonable. For the reasons stated previously, the age grading by the manufacturer of 3+ on the subject product package is not reasonable.

Brickman Decl. and Report at 93. Mohorovic also concludes that the 3+ label is not reasonable, because the manufacturer’s website states that the states that Calico Critters Yellow Labrador Twins toy can be given to children under two years old with adult supervision. See Mohorovic

⁶⁵Although Epoch Everlasting does not cite Dr. Pollack-Nelson’s report as part of its undisputed facts, the Court “may consider other materials in the record.” Fed. R. Civ. Pro. 56 (c)(3).

⁶⁶Although Epoch Everlasting does not cite Dr. Pollack-Nelson’s deposition as part of its undisputed facts, the Court “may consider other materials in the record.” Fed. R. Civ. Pro. 56 (c)(3).

Decl. and Report at 25 (“The subject products were labelled ‘3+’ and ‘Not for children under 3 years.’ This is the manufacturer’s stated intent, but it is not reasonable.”). See also MSJ Response at ¶ 17, at 10. Because (i) Epoch Everlasting does not provide any undisputed facts that the “3+” label is reasonable in its MSJ; and (ii) the Plaintiffs’ and Epoch Everlasting’s experts dispute that the label is reasonable, the Court cannot conclude soundly that the label for children ages 3 and up is reasonable as a matter of law -- a jury would have to make this determination.

Further, for similar reasons, the Court cannot conclude soundly that the second and third § 1501(b) factors indisputably weigh in Epoch Everlasting’s favor. In its MSJ, Epoch Everlasting does not assert any facts relevant whether “the advertising, promotion, and marketing of the article” is “intended for use by children under 3 years (36 months) of age,” or “whether the article is commonly recognized as being intended for children under 3.” 16 C.F.R. § 1501.2(b). See MSJ ¶¶ 1-6, at 3-4. Epoch Everlasting’s repeated assertions that the “Yellow Labrador Twins were . . . intended for children three and up,” and that the toy was “tested to Consumer Product Safety Commission ([‘CPSC’]) regulations and certified as being appropriate for children ages 3 and up,” MSJ ¶¶ 1-2, at 3 -- even if these assertions were undisputed facts, see MSJ Response § II(A) ¶¶ 1-2, at 3-4 -- do not help the Court resolve the § 1501.2(b) test, because they are conclusory assertions with no evidentiary foothold, and lack sufficient detail to satisfy the three-factor § 1501.2(b) test. If the Court looks beyond the facts that the parties present in the MSJ and MSJ Response, see Fed. R. Civ. Pro. 56(c)(3), to the experts’ depositions and reports that the parties reference in their filings, a more detailed, if conflicting, record emerges, see MSJ ¶¶ 1-6, at 3-4 (citing Masterson Depo.); MSJ Response § II(A) ¶¶ 1-6, at 3-7 (citing Pollack-Nelson Depo., Mohorovic Decl. and Report, and Brickman Decl. and Report). The experts provide more detail relevant to the § 1501.2(b) factors, but disagree regarding how the Calico Critters Yellow Labrador

Twins were marketed, advertised, promoted, and commonly recognized. Compare Pollack-Nelson Report at 11-37, 51-53 (discussing the marketing, display, promotion, advertising, and common recognition); Pollack-Nelson Depo. at 46:9-13 (agreeing that it is her opinion that they toy “is not marketed to children younger than age . . . 3”), with Masterson Depo. at 68:22-24 (Epoch Everlasting’s marketing and advertising representative stating that she does not know if Epoch Everlasting has ever advertised or promoted the toy to children younger than three years old); Mohorovic Decl. and Report at 25-27 (asserting that the “subject products were intended by the manufacture[r] to be used by children under 3” under all three § 1501.2(b) factors); Brickman Decl. and Report at 76-90, 92-103 (discussing the toy’s advertising, promotion, marketing, and recognition). For instance, Mohorovic disagrees with Dr. Pollack-Nelson that the toy was intended for children solely older than three years and up; he argues:

The subject products were labelled “3+” and “Not for children under 3 years.” This is the manufacturer’s stated intent, but it is not reasonable based on application of the other relevant factors provided below.

...

The manufacturer’s website FAQs from 2014 to 2019 included the following:

“Q1: I want to buy my child Calico Critters. How old should she be to play with them?”

Answer: Calico Critters have small parts so should only be given to children under 2 with adult supervision. Three years old is the best age to introduce Calico to your child, but maybe don’t buy the sets with very small accessories.”

There is proof of this messaging by the manufacturer resonating in the public domain. In an article, Best Calico Critter Toys in 2020, the author echoed the FAQs with the following, “Babies under the age of 3 can also play with Calico Critters but under strict adult supervision.” Learning Express, a toy retailer and distributor of Calico Critters states, “Calico Critters have small parts so they should only be given to children under 2 with adult supervision. We recommend Calico Critters for children ages 3 and up.” Even the Today Show identified Calico Critters among The Best Toys for 2-Year-Olds 2020, “At 2 and 3, toddlers are often pretending to be Mommy or Daddy and working through ideas about separation.

This one features little animal critters.” Finally, an article entitled, Very Best Toys for Toddlers: 2 and Up, from the website “Chronicles of a Babywise Mom” features Calico Critters.

On the Calico Critters website, Epoch promotes the product as an award-winning product “for collectors of all ages. . . . Particular attention should be on the word “solely.” Since the manufacturer’s stated intent includes children “under 2” and “all ages,” the subject products were not “solely” intended for use by children 3 years of age or older. Therefore, the regulation does apply to Subject Products.

The marketing of the Subject Products on Walmart’s website is conflicting. A disclaimer indicates that the content is provided by “manufacturers, suppliers and others.” The marketing content in one section states that the age range is “3 years and up” while under “Specifications” the age range is listed as “2 years.”

Mohorovic Decl. and Report at 25-27 (footnotes omitted). The experts, therefore, dispute the factual basis for the three § 1501.2(b) factors. Because Epoch Everlasting asserts no undisputed facts relevant to the three § 1501.2(b) factors in its recitation of its MSJ, and because the experts disagree on the Calico Critters Yellow Labrador Twins toy’s advertising, marketing, promotion, and recognition, the Court cannot determine as a matter of law that (i) “the advertising, promotion, and marketing of the article” is “intended for use by children under 3 years (36 months) of age”; (ii) “the article is commonly recognized as being intended for children under 3,” 16 C.F.R. § 1501.2(b); or (iii) that the toy is intended solely for use by children older than three years of age, see 16 C.F.R. § 1501.2(c).

Epoch Everlasting also asserts repeatedly that, “[w]hen Ms. Dedios bought the Yellow Labrador Twins for her two-and-a-half-year-old daughter, she knew the product was intended for children ages 3 and up.” MSJ ¶ 3, at 3. See MSJ ¶ 4, at 3. Even if R. Dedios’ knowledge of the toys target age is an undisputed fact, see MSJ Response § II(A) ¶¶ 3-4, at 4-5 (disputing the characterization that R. Dedios “knew” the toy’s intended age range), Epoch Everlasting cites no law concluding that the buyer’s knowledge is either a factor or dispositive whether the toy was intended solely to sold to children ages three and younger. The Court concludes that an individual

buyer's intent is not relevant to whether a toy was intended for use by children under three years of age. Although the Tenth Circuit has not addressed the issue, the Third Circuit has rejected any consideration of buyer's intent when buying a product. See United States v. Focht, 882 F.2d at 58. The three-factor § 1501.2(b) does not list the individual buyer's knowledge of the toy's age range as a factor. See 16 C.F.R. § 1501.2(b). The three § 1501.2(b) factors discuss only: (i) the manufacturer's stated intent; (ii) the toy's "advertising, promotion, and marketing"; and (iii) how the toy is "commonly recognized as being intended for children under 3." 16 C.F.R. § 1501.2(b). Although "common[] recogni[tion]" might encompass subjective consumer perceptions of the toy, such perceptions are considered only in the aggregate -- i.e. "common" -- and therefore a single buyer's perception of the toy's intended age range cannot be considered. 16 C.F.R. § 1501.2(b). If Epoch Everlasting offered undisputed evidence that the majority of buyers perceive the toy to be targeted at children older than three, the Court would consider such subjective perceptions. Because Epoch Everlasting only presents R. Dedios' perception and no other, the Court will not consider this fact, even if the Plaintiffs did not dispute it.

The Court concludes, therefore, that there are material factual disputes: (i) whether the Calico Critters Yellow Labrador Twins manufacturer's stated intent, including the package's "3+" label, is reasonable; (ii) whether the advertising, promotion, and marketing of the Calico Critters Yellow Labrador Twins toy targeted children younger than three years old; and (iii) whether the Calico Critters Yellow Labrador Twins toy commonly is recognized as intended for children younger than three years old. See 16 C.F.R. § 1501.2(b). See also 16 C.F.R. §§ 1501.2(c); 1500.18(a)(9). Accordingly, the Court, even if it were to consider the three § 1501.2(b) factors, cannot conclude soundly that Epoch Everlasting is entitled to summary judgment on the negligence per se claim, because there are disputed materials facts that preclude the Court from concluding

that the Calico Critter Yellow Labrador Twins was intended solely for children older than three years of age.

II. THE EXPERTS MAY NOT TESTIFY ON THEIR INTERPRETATIONS OF FEDERAL REGULATIONS AND STATUTES, AND THE EXPERTS MAY NOT TESTIFY WHETHER, UNDER THE THREE § 1501.2(b) FACTORS, THE CALICO CRITTERS YELLOW LABRADOR TWINS TOY WAS INTENDED FOR USE BY CHILDREN UNDER THREE YEARS OF AGE, BUT THEY MAY TESTIFY ON THE FACTS RELEVANT TO THE COMPLAINT'S OTHER COUNTS.

Epoch Everlasting requests that the Court strike and limit the testimony of the Plaintiffs' experts, Brickman and Mohorovic, who seek to testify on their interpretations of the federal regulatory scheme banning hazardous toys, including whether 16 C.F.R. §§ 1500.18(a)(9) and 1501.2 ban the Calico Critters Yellow Labrador Twins toy, because the toy is flocked, with small parts that present a choking hazard. See Motion to Limit at 1-2, 6. The Plaintiffs, in response, argue that "[o]ne . . . cannot usually eyeball a toy to determine whether it is a banned, hazardous substance"; therefore, expert testimony is necessary to determine whether the small parts regulation bans Calico Critters Yellow Labrador Twin toy. See Response Motion to Limit at 7-8. The Plaintiffs contend that the same standard applies also to Epoch Everlasting's experts, Toro and Pollack-Nelson, meaning neither of them may testify about their interpretations of the regulations. See Response Motion to Limit at 14. The Court concludes that none of the experts may testify on their interpretations of the regulations, because the interpretation of the regulations is for the Court and not for the jury to decide. See United States v. Richter, 796 F.3d 1173, 1195-96 (10th Cir. 2015). Because the Court concludes that a flocked toy is categorically within the small parts regulation's scope, and therefore intended for use by children under three years of age, see Analysis § I, supra, the Court will not permit the experts to testify whether the Calico Critters Yellow Labrador Twins toy was intended for use by children under three years of age. The experts may testify, however, regarding facts relevant to other counts in the Complaint. See, e.g., Martinez

v. Cont'l Tire the Americas, LLC, No. 1:17-CV-0922-KWR/JFR, 2020 WL 5943691, at *5 (D.N.M. Oct. 7, 2020)(Riggs, J.)(permitting an expert to testify on the standard of care in negligence action, even where federal regulations form part of the duty of care).

Rule 702 of the Federal Rule of Evidence provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education, may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods, and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Rule 702 thus requires the trial court to “determine whether the expert is proposing to testify to (1) scientific, technical, or other specialized knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.” United States v. Muldrow, 19 F.3d 1332, 1337 (10th Cir. 1994). An expert is “required to possess such skill, experience or knowledge in that particular field as to make it appear that his opinion would rest on substantial foundation and would tend to aid the trier of fact in his search for truth.” LifeWise Master Funding v. Telebank, 374 F.3d 917, 928 (10th Cir. 2004). The touchstone of admissibility under rule 702 is helpfulness to the trier of fact. See Werth v. Makita Elec. Works, Ltd., 950 F.2d 643, 648 (10th Cir. 1991).

Although, Epoch Everlasting mentions rule 702, Epoch Everlasting does not attack the qualifications or reliability of either Brickman or Mohorovic in its Motion to Limit. See Motion to Limit at 1-7. Because Epoch Everlasting seeks to limit Mohorovic or Brickman's testimony

“purporting to interpret federal regulations,” Motion to Limit at 4, the Court concludes that Epoch Everlasting’s argument is better understood under both rule 702 and rule 704. Under rule 704, “[a]n opinion is not objectionable just because it embraces an ultimate issue.” Fed. R. Evid. 704(a). Under rules 702 and 704, an expert may give testimony that embraces an ultimate issue so long as the expert’s testimony assists, rather than supplants, the jury’s judgment. See United States v. Richter, 796 F.3d 1173, 1195 (10th Cir. 2015)(“Witnesses are permitted to testify about how the law applies to a certain set of facts, so long as they provide adequate explanations for their conclusions.”); United States v. Schneider, 704 F.3d 1287, 1293 (10th Cir. 2013)(stating that Rule 704(a) allows expert opinion on an ultimate issue so long as the expert explains basis for any summary opinion and does not simply tell the jury what result to reach). See, e.g., United States v. Buchanan, 787 F.2d 477, 483-84 (10th Cir. 1986)(affirming admission of expert testimony that a homemade device was a firearm and therefore needed to be registered with the Bureau of Alcohol, Tobacco, and Firearms); United States v. Logan, 641 F.2d 860, 863 (10th Cir. 1981)(concluding that an expert may testify about how certain funds were classified by law). An expert giving mere legal conclusions without any further explanation is not helpful to the trier of fact. See United States v. Richter, 796 F.3d at 1195 (“[R]ule [704] does not permit an expert to instruct the jury how it should rule, if the expert does not provide any basis for that opinion.”); United States v. Dazey, 403 F.3d 1147, 1171-72 (10th Cir. 2005)(concluding that an expert may not “simply tell the jury what result it should reach[;]” the expert must explain the basis for any summary opinion). The United State Court of Appeals for the Tenth Circuit explains:

Federal Rule of Evidence 704 allows an expert witness to testify about an ultimate question of fact. But the rule does not permit an expert to instruct the jury how it should rule, if the expert does not provide any basis for that opinion. To be admissible, an expert’s testimony must be helpful to the trier of fact. Fed. R. Evid. 702. To ensure testimony is helpful, “[a]n expert may not state legal conclusions drawn by applying the law to the facts, but an expert may refer to the law in

expressing his or her opinion.” United States v. Bedford, 536 F.3d 1148, 1158 (10th Cir. 2008)(internal quotation marks and alterations omitted). “The line between a permissible opinion on an ultimate issue and an impermissible legal conclusion is not always easy to discern.” United States v. McIver, 470 F.3d 550, 562 (4th Cir. 2006). Permissible testimony provides the jury with the tools to evaluate an expert’s ultimate conclusion and focuses on questions of fact that are amenable to the scientific, technical, or other specialized knowledge within the expert’s field. United States v. Dazey, 403 F.3d 1147, 1171-72 (10th Cir. 2005)(“Even if [an expert’s] testimony arguably embraced the ultimate issue, such testimony is permissible as long as the expert’s testimony assists, rather than supplants, the jury’s judgment.”).

As a result, “an expert may not simply tell the jury what result it should reach without providing any explanation of the criteria on which that opinion is based or any means by which the jury can exercise independent judgment.” Id. at 1171. Expert testimony of this sort has been excluded alternatively “on the ground that it usurps the function of the jury in deciding the facts,” or because it “interferes with the function of the judge in instructing the jury on the law.” Id. at 1171 (internal quotation marks omitted). Witnesses are permitted to testify about how the law applies to a certain set of facts, so long as they provide adequate explanations for their conclusions. Id.; see, e.g., United States v. Buchanan, 787 F.2d 477, 483-84 (10th Cir. 1986)(affirming admission of expert testimony that a homemade device was a firearm and therefore needed to be registered with the Bureau of Alcohol, Tobacco, and Firearms); United States v. Logan, 641 F.2d 860, 863 (10th Cir. 1981)(an expert may testify about how certain funds were classified by law).

United States v. Richter, 796 F.3d 1173, 1195-96 (10th Cir. 2015)(concluding that “the district court erred, by permitting [the expert] to provide a bare legal conclusion without explaining the criteria he used to reach that conclusion”).

Although an expert may embrace an “ultimate issue,” Fed. R. Evid. 704(a), an expert may not testify on the requirements of a statute and its regulations: “[i]t is not for witnesses to instruct the jury as to the applicable principles of law, but for the judge,” Specht v. Jensen, 853 F.2d 805, 808 (10th Cir. 1988)(quoting Marx & Co. v. Diners’ Club, Inc., 550 F.2d 505, 509-10 (2d Cir. 1977)). See Christiansen v. City of Tulsa, 332 F.3d 1270, 1283 (10th Cir. 2003)(concluding that is inappropriate for an expert to “state his or her opinion as to legal standards”). For example, in Specht v. Jensen, 853 F.2d 805, 808 (10th Cir. 1988), the Tenth Circuit en banc ruled that opinion

testimony by an attorney-expert on “the entire range of the applicable law” and directing the jury’s “understanding of the legal standards” was inadmissible. 853 F.2d at 808.

Epoch Everlasting relies primarily on U.S. Aviation Underwriters, Inc. v. Pilatus Bus. Aircraft, Ltd., 582 F.3d 1131 (10th Cir. 2009), where the Tenth Circuit concluded that expert testimony “regarding the meaning of” an aviation regulation “violated Fed. R. Evid. 702.” U.S. Aviation Underwriters, Inc. v. Pilatus Bus. Aircraft, Ltd., 582 F.3d at 1150. In U.S. Aviation Underwriters, Inc. v. Pilatus Bus. Aircraft, Ltd., a plane crashed because of engine failure, and the district court permitted expert testimony whether “the pilot operating handbook failed to comply with applicable Federal Aviation Regulations.” U.S. Aviation Underwriters, Inc. v. Pilatus Bus. Aircraft, Ltd., 582 F.3d at 1138. The Tenth Circuit concluded that the district court abused its discretion when it permitted the expert to testify on the meaning of the aviation regulation, reasoning:

The regulation was written in straightforward language and quoted verbatim in Jury Instruction 3.7: “It must be possible to restart an engine in flight. Any techniques and associated limitations must be established and included in the airplane flight manual, approved manual material or applicable operating placards.” To the extent [the expert] was explaining the content of the regulation, he was merely repeating the jury instruction. Nothing about the regulation suggests explanation by an expert was required, and such testimony also violates the rule against experts testifying as to the law governing the jury’s deliberations. Specht, 853 F.2d at 808; see also F.A.A. v. Landy, 705 F.2d 624, 632 (2d Cir. 1983)(affirming district court’s decision to exclude expert testimony about the meaning and applicability of federal aviation regulations because such testimony would “invade the province of the court to determine the applicable law and to instruct the jury as to that law”). Because the testimony regarding the meaning of [the regulation] violated Fed. R. Evid. 702, the district court abused its discretion in admitting it.

U.S. Aviation Underwriters, Inc. v. Pilatus Bus. Aircraft, Ltd., 582 F.3d at 1150-51. The Plaintiffs argue that U.S. Aviation Underwriters, Inc. v. Pilatus Bus. Aircraft, Ltd. does not control, because there are exceptions to the general rule and here,

Mr. Brickman’s and Mr. Mohorovic’s testimony are intended to assist the jury to understand the evidence presented against the backdrop of the federal regulations

governing Defendant Epoch's toys. Given the complex nature of the federal regulations governing children's toys and the testing required under the regulations, the experts' testimony regarding the meaning and application of those regulations will "assist the trier of fact to understand the evidence [and] to determine [] fact[s] in issue" -- not to simply tell the jury what the law is or what conclusion it should reach in the case.

Response Motion to Limit at 13 (quoting Fed. R. Evid. 702).

The Court agrees with Epoch Everlasting that, under rules 702 and 704 of the Federal Rules of Procedure, and Tenth Circuit case law, including U.S. Aviation Underwriters, Inc. v. Pilatus Bus. Aircraft, Ltd., that experts may not testify to their interpretations of the law, but the Court concludes that experts may opine on ultimate issues whether a party violated the law, as long as it is not a bare legal conclusion unsupported by facts. See United States v. Richter, 796 F.3d at 1195-96. The Court has addressed the issue in the past. For instance, in Abraham v. WPX Prod. Prods., LLC, 184 F. Supp. 3d 1150 (D.N.M. 2016)(Browning, J.), the Court did not permit an expert to testify on the legal standard for class-certification, but did permit the expert to testify on factual information relevant to whether common questions predominate. See 184 F. Supp. 3d at 1204-05.

The Court explains:

"[T]he line between an inadmissible legal conclusion and admissible assistance to the trier of fact in understanding the evidence or in determining a fact in issue is not always bright." Burkhart v. Wash. Metro. Area Transit Auth., 112 F.3d 1207, 1212 (D.C. Cir. 1997). To resolve whether an expert's statement is a legal conclusion, courts should "determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular. If they do, exclusion is appropriate." Burkhart v. Wash. Metro. Area Transit Auth., 112 F.3d at 1212 (quoting Torres v. Cty. of Oakland, 758 F.2d 147, 151 (6th Cir. 1985)). See United States v. Perkins, 470 F.3d at 158 (directing courts to consider whether any terms employed have a specialized legal meaning).

Here, the [Expert] Report contains numerous statements that have a "distinct and specialized meaning in the law." Burkhart v. Wash. Metro. Area Transit Auth., 112 F.3d at 1212 (quoting Torres v. Cty. of Oakland, 758 F.2d at 151). See, e.g., [Expert] Report at 10 ("The questions that will consume significant trial time, questions that will be subject to disagreement and expert testimony at trial, are common to the class."); id. at 13 ("The leases in this case point clearly to

common questions.”); *id.* at 22 (“The Class Representatives’ Claims are Typical.”). Commonality, typicality, adequacy, numerosity, superiority, and predominance are all legal terms of art. *See* Fed. R. Evid. 23. Accordingly, whether the case meets rule 23’s class certification requirements is an issue for the Court to decide, not McArthur. *See Specht v. Jensen*, 853 F.2d at 809 (stating that “testimony on ultimate issues of law by the legal expert is inadmissible because it is detrimental to the trial process”). Testimony regarding rule 23’s legal standard will not assist the Court in determining whether to certify a class, because the Court is an expert in the law and needs no guidance from [the expert]. *See Specht v. Jensen*, 853 F.2d at 807; *Burkhart v. Wash. Metro. Area Transit Auth.*, 112 F.3d at 1213 (“Each courtroom comes equipped with a ‘legal expert,’ called a judge, and it is his or her province alone to instruct the jury on the relevant legal standards.”).

Abraham v. WPX Prod. Prods., LLC, 184 F. Supp. 3d at 1204-05.

In another recent example, the Honorable Kea W. Riggs, United States District Judge for the District of New Mexico, permitted an expert to testify on the standard of care in negligence action, even where federal regulations form part of the duty of care. *See Martinez v. Cont’l Tire the Americas, LLC*, No. 1:17-CV-0922-KWR/JFR, 2020 WL 5943691, at *5 (D.N.M. Oct. 7, 2020)(Riggs, J.). Judge Riggs explains:

Generally, an expert in a negligence action may opine on the standard of care and the breach of that standard. There is “no error with an expert applying the legal or industry standards to the facts in determining if a defendant’s conduct was violative of the standards of a profession or industry.” *Lua v. QBE Ins. Corp.*, No. 18-CV-01233-KLM, 2019 WL 5104477, at *3 (D. Colo. Oct. 11, 2019). . . . However, an expert is not prohibited from testifying about the standard of care in his industry merely because federal regulations form part of those standards.

Therefore, generally[, the expert] may testify based on his experience, skills, and education his understanding of the industry standards on safely maintaining and operating commercial vehicles, and instances in which [truck’s owner] or Plaintiff Felipe Martinez failed to follow those practices as to the truck at issue. However, the Court cautions that [the expert] may not simply state that [the truck’s owner] or Plaintiff Felipe Martinez violated federal regulations practice without directly referencing specific factual instances in this case relevant to the truck or action in this case. That would be a mere legal conclusion that would not assist the trier of fact understand an issue in the case.

The Court finds that [the expert’s] expert testimony on the standard of care in safely maintaining and operating commercial vehicles will assist the jury, and the jury will most likely not already have that knowledge. His testimony is based on exceptional knowledge, skill, and experience in the trucking industry.

Martinez v. Cont'l Tire the Americas, LLC, 2020 WL 5943691, at *5 (citations omitted).

Here, the applicable legal standard requires the Plaintiffs to prove that the Calico Critters Yellow Labrador Twins toy (i) was intended for use by children under three years old; (ii) has small parts that present a choking hazard; and (iii) was introduced into the stream of commerce after January 1, 1980. See 16 C.F.R. §§ 1500.18(a)(9). The parties only dispute whether the Calico Critters Yellow Labrador Twins toy was intended for use by children under three years of age; it is undisputed that the Calico Critters Yellow Labrador Twins toy has small parts -- its pacified and bottle accessories -- which present a choking hazard and was introduced into interstate commerce after January 1, 1980. In its Analysis § I, supra, and in its Law Regarding section, the Court discusses how to determine whether a toy is intended for use children by under three years of age. Section 1501.2 provides a non-exhaustive list of toys intended definitively for use by children under three years of age, which includes “flocked animals,” and provides three factors to determine if any other toys are intended for use by children under three years of age: (i) “the manufacturer’s stated intent (such as on a label) if it is a reasonable one”; (ii) “the advertising, promotion, and marketing of the article”; and (iii) “whether the article is commonly recognized as being intended for children under 3.” 16 C.F.R. § 1501.2. If, however, the toy is “solely intended for use by children 3 years of age or older,” the small parts regulation does not apply. 16 C.F.R. § 1501.2(c). The parties’ and their experts’ legal dispute whether a flocked toy is intended for use by children under three years of age under § 1501.2 is for the Court, not for the jury, to decide; the experts, therefore, may not testify to their interpretations of which toys are within the scope of §§ 1500.18(a)(9) and 1501.2. See United States v. Richter, 796 F.3d at 1196; Specht v. Jensen, 853 F.2d at 809. Because the Court concludes that any toy listed in § 1501.2(a) -- including flocked toys -- is intended definitively for use by children under three years of age, see Analysis

§ I, supra, the experts may not testify, under the three § 1501.2(b) factors, whether the Calico Critters Yellow Labrador Twins toy are intended for use by children under three years of age.⁶⁷

⁶⁷If the Court had concluded that flocked toys are not intended definitively for use by children under three years of age under 16 C.F.R. § 1501.2, then the Court would have permitted the experts to testify whether, under the three § 1501.2(b) factors, the Calico Critters Yellow Labrador Twins toy was intended for use by children under three years of age. See Fed. R. Evid. 702, 704; United States v. Richter, 796 F.3d at 1196; Specht v. Jensen, 853 F.2d at 809. Although experts are not permitted to provide pure legal conclusions, experts are “allowed . . . to opine on an ‘ultimate issue’ to be decided by the trier of fact,” United States v. Schneider, 704 F.3d at 1293 (quoting Fed. R. Evid. 704(a), and citing United States v. Dazey, 403 F.3d at 1171). Accordingly, as long as the experts do not “‘simply tell the jury what result it should reach,’” and as long as they explain the basis for their conclusions based on the three § 1501.2(b) factors, the Court would have permitted the experts to “opine” whether the Calico Critters Yellow Labrador Twins toy was intended for children ages three and younger. United States v. Schneider, 704 F.3d at 1293 (concluding that it was permissible for doctors to “to opine that ‘the clinic was at fault’ for illegal drug distribution, and . . . to opine that [another doctor] ‘engaged in health care fraud’” resulting in death, because the doctors did not tell “the jury reach a particular verdict” and “explain[ed] at great length their observations from the evidence”).

For instance, the experts would have been permitted to testify to facts related to the three § 1501.2(b) factors: (i) whether the “3+” label on the Calico Critters Yellow Labrador Twins toy’s throw-away packaging is reasonable; (ii) the steps taken to advertise, promote, and market the toy; and (iii) how the toy is commonly recognized. See 16 C.F.R. § 1501.2(b). Based on the facts relevant to the three § 1501.2(b) factors, the experts then would have been permitted to opine on the “ultimate issue,” Fed. R. Evid. 704(a), i.e., whether the Calico Critters Yellow Labrador Twins toy was intended for children younger than three years of age, see United States v. Schneider, 704 F.3d at 1293.⁶⁷ See also United States v. Richter, 796 F.3d 1173, 1195 (10th Cir. 2015)(concluding that an expert may give testimony that embraces an ultimate issue so long as the expert’s testimony assists, rather than supplants, the jury’s judgment). Because the Court has concluded that flocked toys are intended definitively for use by children under three years of age, none of this testimony is necessary.

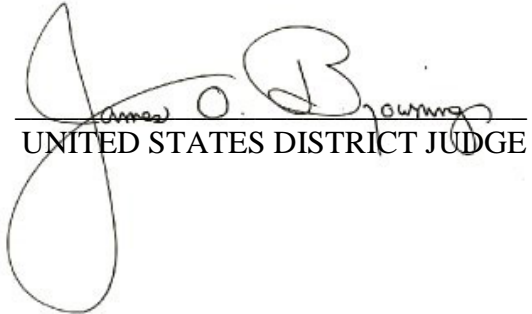
In addition, the Court notes that, even if it was an issue whether the Calico Critters Yellow Labrador Twins toy was intended for use by children under three years of age, none of the experts would have been permitted to testify to the “Age Determination Guidelines issued by the Commission staff in September 2002, and any successor to such guidelines,” 14 U.S.C. § 2052(a)(2)(D), because that factor is not part of the §§ 1500.18(a)(9) and 1501.2 inquiry. Although 20 U.S.C. § 2052(a)(2) and 16 C.F.R. §§ 1200.2(a), (c) rely on three of the same factors as 16 C.F.R. § 1501.2(b), they use an additional fourth factor -- the “Age Determination Guidelines issued by the Commission staff in September 2002, and any successor to such guidelines” -- to determine whether a product is intended for a child twelve years of age or younger. 20 U.S.C. § 2052(a)(2); 16 C.F.R. §§ 1200.2(a), (c). For instance, Dr. Pollack-Nelson spends much of her report discussing the Age Determination Guidelines, see Dr. Pollack-Nelson Report at 7-54, but whether a product is intended for a child twelve years of age or younger is not the inquiry in this case. The experts, therefore, may not testify about the Age Determination Guidelines. Facts

The Court concludes that the experts may, however, testify to facts relevant to other counts in the Complaint, such as negligence. See, e.g., Martinez v. Cont'l Tire the Americas, LLC, 2020 WL 5943691, at *5 (“[A]n expert is not prohibited from testifying about the standard of care in his industry merely because federal regulations form part of those standards.”). The Court attaches to its Memorandum Opinion and Order the four expert reports as exhibits -- Brickman’s, Mohorovic’s, Toro’s, and Dr. Pollack-Nelson’s reports -- with redactions. The Court has redacted the report’s portions where the experts interpret disputed legal standards, which, although helpful to the Court, are for the Court to decide, and not for the jury. See United States v. Richter, 796 F.3d at 1196; Specht v. Jensen, 853 F.2d at 809. The experts may testify only about the facts and opinions in their report’s unredacted portions. Accordingly, the Court will grant in part and deny in part the Motion to Limit: (i) the Court will not allow the experts to “opine” whether the Calico Critters Yellow Labrador Twins toy was intended for children ages three and younger, because flocked toys are intended definitively for use by children under three years of age; and (ii) the Court will only allow the experts to testify regarding the non-redacted portions of their respective reports related to the Complaint’s other counts, excluding any discussion of the disputed legal standards and whether the Calico Critters Yellow Labrador Twins toy was intended for use by children under three years of age.

IT IS ORDERED that: (i) Defendant Epoch Everlasting Play, LLC’s Motion to Strike and Limit Testimony of Plaintiffs’ Experts Dennis Brickman, PE and Joseph Mohorovic, CPSM, filed November 19, 2020 (Doc. 100), is granted in part and denied in part: the experts may not testify

relevant to the Age Determination Guidelines may nonetheless be relevant to the other counts, including negligence; accordingly, the experts may testify to these relevant facts as long as they do not discuss the Age Determination Guidelines.

on their legal interpretations that go to negligence per se, but may testify to facts related to the other counts; and (ii) Defendant Epoch Everlasting Play, LLC's Motion For Partial Summary Judgment on Count III of Plaintiffs' First Amended Complaint -- Negligence Per Se, filed December 1, 2020 (Doc. 105), is denied.



UNITED STATES DISTRICT JUDGE

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